



# Insulin Dependent Diabetes Trust

January 2004 Newsletter



## 2004 IDDT's 10th anniversary!

### A time for celebration or for sadness?

*"I would just like to thank you very much for your help and advice I needed so badly when my symptoms of hypoglycaemia disappeared. Since going on to pork insulin they have pretty much returned in full, in what seems a very rapid time."*

This is a quote from one of our new members, someone treated from diagnosis with synthetic GM insulin and someone who had never been given the choice of using animal or synthetic insulins - until that is, he found IDDT. Only people with diabetes and their carers can truly realise the full impact that loss of hypo warnings has on their lives but even those of us that can only imagine what it must be like, can

appreciate the huge improvement that regaining hypo warnings must make. For this one man, IDDT made a real difference but he is one of many and we should celebrate our 10th Anniversary!

IDDT was formed in 1994 with very specific and clear aims - firstly to achieve recognition that some people cannot tolerate synthetic GM insulin, then very misleadingly called 'human' insulin. Secondly we wanted the choice of natural animal insulins to remain available not only for this group of people but for people in the future who may the experience problems with synthetic GM insulins.

In 1994 five angry people joined together to form IDDT. We had just two things in common, our need for animal insulin and our experiences of not being listened to or believed by our doctors or by Diabetes UK, then the British Diabetic Association, when describing the adverse effects of 'human' insulin. We all experienced being dismissed as neurotic or

extremist with some sort of axe to grind. We all had voluntary roles within Diabetes UK and so knew for certain that nearly 3000 other people had complained to them of similar experiences, so if we were neurotic extremists, so were 3,000 other people! Of course, we also knew that the way 'human' insulin was introduced left a great deal to be desired. It was foisted on the UK market with indecent haste with no large-scale long-term trials comparing animal and synthetic GM 'human' insulin and with no evidence of benefit to people with diabetes. 84% of the diabetic population were changed to synthetic insulin on the assumption that it was better, not on the evidence that it was better. Is there any wonder that we were angry?

**But with our anger was also disappointment and disbelief.**

Synthetic 'human' insulin was a new drug and the first drug ever to be produced by genetic modification so we naturally had expectations of our doctors and healthcare professionals and especially the 'experts' in diabetes. We expected them to be aware that there may be adverse reactions to a new insulin and to believe their patients when they complained of problems that had occurred after changing to the new GM insulin. We expected them to simply change people back to the animal insulin that had suited them well in the past. Indeed, we expected them to report the adverse reactions to the Committee on Safety of Medicines and to the insulin manufacturers. We also expected them to be very cautious in the use of 'human' insulin until more research had been done to provide the evidence that they and their patients needed. Rarely did we see this happen.

We were angry and disappointed that Diabetes UK chose not to publish the research that they had carried out into the reports of adverse effects that 'human' insulin caused. We were angry that they did not use their considerable influence to widely publicise the difficulties that were occurring with synthetic GM insulins or to ensure that good quality research was carried out to investigate these difficulties. They did send a petition to the insulin manufacturers but it is difficult to believe that they really thought that this was likely to influence the strategies of multi-national drug companies!

We weren't disappointed with the drug companies as we were aware that their job was, and is, to make profit for their shareholders but we were angry and shocked at the tactics they used to make sure that 'human' insulin became first line treatment. Perhaps it was the first time that we realised that it is the might and power of multi-national pharmaceutical companies that actually dictates our treatment, until then we had naively believed that our doctors did this!

**So should we greet IDDT's 10th Anniversary with celebrations or sadness?**

Perhaps the answer is both. Yes we are sad:

- 10 years later we are still fighting for continued availability of animal insulins so that choice is available but the sadness is greater because we are doing this alone, without the support of the majority of medical and nursing professionals or national and international diabetes associations.
- It is sad that there is a lack of respect for people with diabetes and their carers, shown by their experiences not being considered as valid evidence - a polite way of saying they are ignored or not believed. This is a group of people who are able to manage their own diabetes for the 365 days a year with a couple of 30 minute clinic visits a year, yet their experiences fall on deaf ears. The reality is that many people who want to change animal insulin still have to go into battle with their diabetes teams to do so.
- We are sad that people with diabetes are not being given the informed choice of insulin treatment to which they are entitled and diabetes teams are prepared to risk breaching this very basic right of patients.
- Perhaps the greatest sadness is that 10 years on, insulin treatment is not based on evidence of benefit for patients - there is none! But perhaps even more disappointingly, the leaders in the diabetes community do not seem concerned by this!

**But on the 10th Anniversary of the formation of IDDT we can celebrate:** 10 years later IDDT has grown from 5 angry people to an international

organisation with members in countries throughout the world. Had the accusations that those 5 angry people were neurotic extremists been true, then IDDT would never have become the independent international patient/carer organisation that it is today. If our case that synthetic GM insulins are not suitable for everyone is not justified, then our opponents would have wiped the floor with our case long ago. If our experiences did not reflect those of many other people, then IDDT would not be in existence now - we would have collapsed for lack of support and lack of funds.

### So 2004 is a year to celebrate!

- We still do have animal insulins in the UK and there are still over 30,000 people using them.
- We do have an acknowledgement from the Dept of Health that some people are better suited to animal insulins.
- We have gathered information from large numbers people in various countries who have experienced difficulties with GM insulin.
- The Cochrane Review has demonstrated that our concerns are justified. It confirms that synthetic GM insulins are not superior to animal insulins, that the majority of the research that has been done is 'methodologically poor' and that the vital research into complications, mortality and quality of life has never been done.

We should celebrate that we are perhaps the only international patient/carer organisation that is entirely independent, unfettered and uninfluenced by pharmaceutical industry or their funding and we should celebrate the freedom that this provides. We are free to question, to criticise and to praise and we only have one responsibility, our duty to people with diabetes.

10 years on, we should celebrate the formation of IDDT. Every letter, e-mail or phone call that starts with 'You have changed my life....' confirms this!

## The Black Triangle

### “Report any adverse reactions to CSM”

MIMS is an independently written monthly publication designed as a prescribing guide for GPs and it is sent to all medical practitioners free of charge. Various symbols are used to help readers. A black triangle is used to show that ALL suspected adverse or unexpected reactions, however minor, should be reported to the Committee on Safety of Medicines [CSM] using the Yellow cards scheme, even though it is flawed it is the only system we have. The black triangle is usually used for new drugs but this classification seems to go on for some time.

We know that there seems to be an unwillingness to report adverse reactions to the CSM so it may be useful for readers to know which insulins have a black triangle.

**Quote from MIMS** “Report any adverse reactions to CSM” for the following:

<b>Novo Nordisk</b>	<b>Aventis</b>
<b>NovoRapid</b> [aspart, short-acting analogue]	<b>Lantus</b> [glargine, long-acting analogue]
<b>NovoMix 30</b> [pre-mix aspart and protamine insulin aspart]	<b>Insuman Rapid</b> [short-acting analogue]
	<b>Insuman basal</b> [intermediate-acting human]
	<b>Insuman Comb</b> [pre-mix human neutral and isophane]

Remember to ask your doctor to report any suspected adverse reactions because it helps to build up a picture of the drug/insulin and this will help to ensure its safety, inform prescribers and provide a more informed choice for patients in the long run.

## First Celebration Of 2004

### Welcome to IDDT- India

We are delighted to welcome India into the IDDT-International fold and we say a warm welcome to people in India. It is great that we are widening our presence. The site is very informative and provides information pertinent to both medical and healthcare professionals as well as to people with diabetes.

Because of the situation in India, IDDT-India is set up differently from IDDT in other countries in that the Trustees in India are all leading medical experts in diabetes and we are very grateful for their time and commitment. However, in other respects IDDT-India functions in the same way - people can become members and any donations will be sent to IDDT in the UK.

The formation of IDDT- India is unrelated to the support IDDT and many of you offer to the children and young people with diabetes at Dream Trust but our involvement has helped us to realise the enormous problem that faces people with diabetes in India.

As you know in India many people cannot afford the insulin they need and when they can, their choice is often governed by cost. It is essential that it is known that animal insulins are available in India, that they are **not** inferior to synthetic GM insulins that are now being marketed to them and that they are cheaper. We are grateful to all the people who have helped in the formation of IDDT-India and to the Board of Trustees.

If you have internet access, do visit the website there's interesting information for everyone! You will find it at [www.iddtindia.org](http://www.iddtindia.org)

### Dream Trust Nagpur, India

#### Unwanted, in-date insulin saves lives!

In poor countries the cost of insulin to treat one child can be 50% of

a family's income and children die for lack of affordable insulin. IDDT collects and sends unwanted, in-date insulin to help poor children at Dream Trust in India, a diabetes clinic for children and young people with diabetes.

Many thanks to everyone who has already sent us insulin but please look in your fridge to see if you have any unopened, in date insulin, or any other diabetes supplies and send them in a 'jiffy bag' to IDDT, PO Box 294, Northampton NN1 4XS

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## Good News! Astralian Government Class Beff Insulin As An 'Essential Medicine'

The fiasco in Australia when imports of beef insulin were suddenly stopped because of one 'Mad Cow' in Canada, showed just how easily supplies can be halted. Ian Kershaw who runs the website for IDDT-Australia contacted his MP to try to ensure that the beef insulin he and many others need, will continue to be available. His MP asked a Parliamentary Question and the Australian Minister response was that beef insulin is classed as an **essential medicine** for people who cannot tolerate synthetic 'human' insulin. It is a major step forward because:

- the Australian government is publicly acknowledging that some people cannot tolerate synthetic insulin
- classification of beef insulin as an essential medicine must mean that the government has a duty to ensure continued access to beef insulin for people who need it.

This is recorded in the Australian Hansard for all to see. It will help people in Australia and is a major breakthrough for people in other countries too. It is the first government statement that animal insulin is an essential medicine and as such must remain available. It remains to be seen just how this would be put into operation, should

manufacturers decide to discontinue production...Nevertheless, we congratulate the Australian government for listening to people with diabetes and truly acknowledging their needs. Let us hope that other countries follow their lead.

from further destruction of their insulin-producing cells. In addition, patients with fully established diabetes possibly could have their diabetes reversed.”

Clearly there is still along way to go, but things are looking more promising!

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## World Diabetes Day Announcement

November 14th 2003

- **US Research Breakthrough for Type 1 Diabetes**

US researchers at Massachusetts General Hospital have been able to halt, and even reverse, Type 1 diabetes in mice. The researchers had already shown that injecting diabetic mice with spleen cells from healthy mice re-educated their immune systems so that they could accept an islet cell transplant. However, the mice unexpectedly began to produce islet cells that could secrete insulin themselves. This latest research found that this only happened if the mice had been given a specific type of spleen cell that can be distinguished from other spleen cells by their lack a particular molecule called CD45. It is the cells without CD45 that are the precursors for pancreatic islets and they have a distinct function that has not previously been identified for the spleen.

To double check their findings, researchers carried out the same treatment giving female diabetic mice spleen cells from healthy male cells. In the diabetic mice that achieved long-term normal glucose metabolism, all the new functioning islets had significant numbers of cells with Y chromosomes which means that they must have come from the male donors.

Dr David Nathan, director of the hospital's Diabetic Centre, says: "These exciting findings in the mouse model Type 1 diabetes suggest that patients who are developing this disease could be rescued

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## IDDT - The Voice For Choice

Last year's IDDT Annual Conference gave one loud and clear message for our anniversary year - that IDDT should be the **voice for choice** while recognising that choice is no choice at all unless it is an **informed choice**.

In his first speech as Health Secretary, John Reid said that the NHS will become a more personal service, focused on the needs of patients not providers and that capacity will be increased alongside an extension of personal choice for patients. It remains to be seen what Mr Reid means by 'personal choice for patients' but we would hope that he remembers it means a great deal more than just offering a choice of the NHS services we use. For people with long-term conditions such as diabetes, personal choice is more than simply choosing where or when we have our treatment. It is about sharing knowledge and information and about patients being partners in decisions about their healthcare.

As readers are aware, IDDT has long held this view and it is good to see it being expressed by the Long-term Medical Alliance [LMCA] in its response to the government's consultation, "Fair for all personal to you: Choice responsiveness and equity in the NHS and social care."

So Mr Reid has a big job on his hands! To achieve these vital changes there has to be a shift in the relationship between the NHS, the doctors and healthcare professionals within it, and patients. There has to be:

- a commitment by health professionals to share knowledge and information with patients about all treatment options and this information must be based on unbiased evidence, not drug company sales literature.
- a commitment that the views of patients will carry equal weight in decision making.

At the same time, many patients will need to develop the courage and confidence to be equal partners in this process.

Every day we manage and take responsibility for our own diabetes, sometimes better than others and some people better than others, but we all do it. Therefore, it is almost unbelievable that knowledge and information is not shared with us and that we are not equal partners in decisions-making about our health. While this concept may be new to the NHS, it has been discussed in diabetes for many years.

We believe that informed choice involves sharing information about the many aspects of diabetes and its management - different insulin regimes, diet, exercise, and the many other drugs that are often prescribed for us. We firmly believe that everyone requiring insulin treatment should be given an informed choice of synthetic GM or natural animal insulin. They should know that there are different types of insulin in case they have problems that can't be resolved and they should not have to enter a battle zone in order to try animal insulin.

### **Do people with diabetes really have an informed choice?**

In the UK diabetes specialist nurses [DSNs] play a large role in the treatment of people with diabetes and often a major role in the decision making process. It is clear from the many reports IDDT receives, that DSNs play a huge role in deciding what insulin someone should use and they even persuade people not change insulins. There are legal issues here because DSNs are not allowed to prescribe and refusing to allow people to change insulin is still a prescribing decision. But the legal position bears little resemblance to the reality in diabetes care. So if we are to achieve an *informed* choice, and the sharing of all information and knowledge then it is vital that DSNs in particular

appreciate that their role has to change.

### **Choice of insulins, pen devices and blood glucose meters: Factors influencing decision making by DSNs in the UK**

This is the title of a recent study [ref 1] and in the light of the present recommendations for patient choice, it is amazing! Even the language contradicts the meaning of the words 'patient choice' - in the first paragraph is the sentence *"The primary aim of this study was to identify which factors influence the thought processes of the DSNs when they are deciding which insulin type, pen device and blood glucose meter is suitable for their patient."*

Who is deciding what insulin type is the most suitable for their patient? Apart from their own involvement in this decision, patients still like to think that those qualified to prescribe ie doctors, will be involved in this decision! This sentence alone, shows that there is a very long way to go before patients are equal part of the decision making process. Anyway, the study was carried out by questionnaire involving 227 DSNs who were asked to respond to statements with strongly agreed, agreed, disagreed, strongly disagreed.

### **Results!**

- DSNs felt that they predominantly chose the insulin type and only nine, 4%, did not autonomously initiate insulin treatment. They thought that patients more often chose the pen device and both had equal choice over meters.
- Most DSNs felt that clinic time was adequate to provide a choice of insulin. Well it would be as 96% of DSNs chose the insulin type anyway! They said that patients were often too shocked to make such decisions - obviously not thought of the possibility of dealing with the immediate situation, then later discussing choice issues! They were less content about the time allocated to pen and meter choice.
- Most DSNs agreed that their personal experience of a given insulin type would affect future choice and this was the top influencing factor on their choice. This was followed by literature

and pharmaceutical production of a particular insulin type. Patient literature explaining insulin types were stocked within most centres [88%]. Lilly and Novo Nordisk insulin and pen devices were stocked in most diabetes centres but availability of CP Pharmaceuticals insulins and Aventis were meagre. [The study was carried out before the introduction of Lantus.] DSNs were ambivalent about whether they would alter their insulin choice if it were immediately available from stock but they would change their choice of pen or meter if they were not stocked.

- Costs of insulin and equipment were least likely to influence choice but the majority of diabetes centres and patients do not pay for their insulin or consumables [strips etc]. Local policies determining exclusive use of an insulin brand may reduce overall costs and be influential. [In our language this means that by using insulin from a particular company, there is a discount.] Sounds like management choice rather than DSN or patient choice!
- Local prescribing policies and pharmaceutical representative support were shown to have a modest influence over choice.

### Key conclusions of the authors

The authors concluded that DSNs are not giving newly diagnosed people with Type 1 diabetes choice, despite this group being in the younger age group. To 'empower' patients, suggests a shift in emphasis from the traditional model of '*doctor knows best*' [in this case '*DSN knows best*'!] to a more patient centred approach. As choice is so important they question whether prescriptive protocols and pharmaceutical contracts are appropriate.

### So how is informed choice ever to be achieved?

The study describes the DSN role as 'pivotal and often autonomous' in starting insulin treatment but shows that the greatest factor in influencing their choice of insulin is their own experience. As most of them trained after the introduction of GM insulin they have little or no personal experience of pork and beef insulins, so will we ever get to a position of patients being given a fully informed choice of insulin?

Clearly the other important factor that this study highlights is local

pharmaceutical contracts ie discounts for sole use of a brand of insulin. It is obvious that this happens because certain areas are obviously Novo Nordisk and others are Lilly! But for patients to have an informed choice of insulin and for Mr Reid's wishes to come true, these local deals have to stop.

While pharmaceutical representative support was shown to have only a modest influence over choice, it shouldn't have any at all! This is biased and not evidenced based.

Perhaps of greater concern is that at no point did the study raise the issue of the decisions of DSNs being based on evidence from research. If DSNs have this 'pivotal and often autonomous role' in starting insulin treatment despite the questionable legality of this, then surely patients should expect that these decisions are based on evidence from independent research.

### IDDT's actions for our Anniversary year, 2004

The delegates at the Annual Meeting 2003 came to a clear conclusion - people requiring insulin treatment are not given an informed choice of treatment, especially in relation to insulin types. If professionals are not doing it we must and this is the main objective for 2004 - reaching people with diabetes and sharing knowledge and information with them. IDDT has to become the 'Voice for Choice'!

Ref 1 Pract Diab Int Sept 2003 Vol 20 No7



## Aspartame

In our last newsletter we told you about John who by totally cutting out aspartame [also known as Nutrasweet] from his diet found that the increasing joint/muscle pains and fatigue that he had been experiencing were greatly reduced. We asked you to tell us about your experiences with aspartame and we are grateful to all those

who responded.

### **But first, just for the record, what is aspartame?**

It was first intended as an ulcer drug and the scientist developing it happened to taste it and found that it was sweet. It is composed of 3 chemicals 50% phenylalanine, 40% aspartic acid and 10% methanol. Ingesting high amounts of phenylalanine results in a build up of it in the brain and this potentially decreases the amount of serotonin in the brain. This in turn can result in depression and mood disorders. Once ingested aspartame converts to formaldehyde and formic acid. [For those who did biology at school formaldehyde is the embalming fluid used to keep animals for dissection and is a Class A carcinogen!]

The FDA in the US refused to approve aspartame for more than eight years because of seizures and brain tumours it produced in animal studies. In 1981 it was finally approved for use in dry goods and since then it has been approved for use in every type of food product. In 1994 The US Dept of Health and Human Resources reported more than 90 symptoms of aspartame poisoning including headaches, weight gain, muscle spasms, heart palpitations, nausea, fatigue, anxiety attacks, fibromyalgia and so the list goes on!

### **So what did you tell us?**

- Quite a few people have found that aspartame has caused them very real problems but all of them had to find this out for themselves, usually via the internet and not from their doctor or health professional. They found that cutting out all food and drinks containing aspartame reduced or removed their symptoms.
- One of our members said that aspartame caused her to have fibromyalgia symptoms. Fibromyalgia is a collection of symptoms rather than a specific disease and characterised by widespread pain for more than 3 months and one of the other symptoms is sleep deprivation. Interestingly recent studies into causes of these sleep problems have identified a deficiency in serotonin [remember above!] in the central nervous system and the result is Disordered Sensory Processing where the brain registers pain when others

might experience a slight ache or stiffness.

- One lady told us she had suffered with interstitial cystitis [chronic inflammation of the bladder] for over 10 years. Her doctor prescribed antibiotics each time and she was referred to a urologist for tests and surgery with no success. She then found the website of the Interstitial Cystitis Support Group where one of the suggestions was to exclude certain foods from her diet for two weeks and then bring them back in one by one to find out if any of them produced symptoms of cystitis. She did this and found that an hour after drinking a low sugar drink containing aspartame, she had cystitis symptoms and even the tiny bit of aspartame in reduced sugar Tomato Sauce caused a reaction. She has cut out aspartame from her diet and has been free from interstitial cystitis for 6 months.

Clearly many people are unaffected by aspartame but it certainly has adverse effects on some people and as the article in the last Newsletter said, as a group, people with diabetes probably consume more aspartame than any other group of people.

**Note: If you want information about fibromyalgia, contact the Fibromyalgia Association UK on 0870 2201232 or an interesting website [www.fibromyaliasupport.com](http://www.fibromyaliasupport.com)**

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## **Action! IDDT Goes To Westminster**

In the UK we have watched the discontinuation of pork and beef insulin in countries around the world. We have done all we can to help people but the discontinuations have progressed. People have been denied the insulin they need, the insulin that suits them best and for no other reason than the commercial decisions of the pharmaceutical companies, in other words, profit.

**Can we let this happen in the UK?** The answer to this is simple - not without a fight.

**Can we actually stop it happening in the UK?** We don't know but we have to do all we can to try to stop it. We are also realistic in that we know that the power, the money and the influence of the insulin manufacturers cannot be underestimated. We also know that most of our doctors and healthcare professionals do not seem willing to use their power and influence to support people who need animal insulins or even to support choice.

**Why are we asking these questions now?** There are individual people in some EU countries who are still managing to obtain Novo Nordisk animal insulin by one means or another, but they have been told that manufacture will cease in 2005. So we have to wonder how likely it is that Novo Nordisk will continue to produce their pork insulin just for the UK market?

**The UK situation is different, let's take a look:**

It has always been different because we have two suppliers of animal insulins - the multi-national company, Novo Nordisk and also by British-based CP Pharmaceuticals who make pork and beef insulins and do not make synthetic insulin. So we have always had choice, even if we haven't been given that choice.

In other countries, two multi-nationals Novo Nordisk and Eli Lilly have been the main suppliers. While they are business competitors for insulin sales, strangely [or not so strangely!] their commercial decisions to discontinue animal insulins have been the same, right down to the timing and the order in which the insulins have been discontinued. This has left people with no choice but to use synthetic GM insulins, something that both companies wanted to achieve if for no other reason than it is much cheaper to only have to produce one type of insulin.

**Don't panic!**

IDDT has to consider the possibility that 2005 could be the year in which Novo Nordisk decide to discontinue pork insulin in the UK. IDDT would be failing in our duty if we did not take this possibility seriously. At the same time, we emphasise that we have NOT formally been

told this, but in October 2002 when Novo Nordisk agreed to continue the supply of pork insulin in the UK, they did say that this strategy would be reconsidered from time to time. So please don't panic! To *Novo Nordisk pork insulin users, remember that CP Pharmaceuticals produce a range of pork and beef insulins in vials and cartridges for pens.*

**Having said don't panic, we cannot sit back and let this possibility become a reality.**

We have again contacted the International Diabetes Federation and they happened to be meeting Novo Nordisk a week later and promised to let IDDT know the position, but they did not. This lack of response is open to interpretation but they do not appear to want to support patients in the developed world who need animal insulin.

Over the years we have had dialogue with the Dept of Health and achieved a statement from them in 1998 acknowledging that some people are better suited to animal insulin and should continue with treatment with animal insulin. But the Medicines Control Agency [now MHRA] also part of the Dept of Health, has continually stated that the insulin manufacturers have said that they will continue to supply for the foreseeable future and more importantly for us, that they cannot interfere with the commercial decisions of companies.

The '*foreseeable future*' is a meaningless statement and offers no reassurance. But having admitted that some people need animal insulin, for the Dept of Health to then state that they '*cannot interfere with commercial decisions*' means that they are not, or cannot, offer protection to this group of people. What exactly does the Dept of Health expect to happen to them? The logical conclusion from these two statements is that the Dept of Health is prepared to let this group of people suffer severe adverse reactions affecting their health, their life and that of their families. This is totally unacceptable and has left us with no other course of action than to enlist the help of our politicians.

## Westminster visits

With the help of a political adviser, we have already visited the Houses of Parliament to meet MPs, MEPs and a member of the House of Lords all of whom have a special interest in health. We received sympathetic, supportive and very helpful responses from all of them and they all agreed to follow this up, including asking Parliamentary Questions, writing letters to the insulin manufacturers and other relevant people and organisations. Several Parliamentary Questions [PQs] have been asked, answered by the Minister of Health responsible for diabetes, Rosie Winterton, and are being followed by pursuant Questions as her answers have not given the reassurances that we need. PQs not only raise the issue in the House but they and the Minister's responses are recorded in Hansard for all to see and forever. So no one, including government, can later say that they were unaware of the problem.

It may be that we will ask you help by contacting your MP and MEP but in the meantime we are following the parliamentary process and we will keep you informed of our progress. We would like to express our gratitude to all the politicians who have given up their time to meet with us and to follow up our very real concerns.

## But you can help now!

In 2004, IDDT will be taking steps to try to reach the 30,000 people who are using animal insulin to ask them to support our battle to maintain supplies. But this is no longer a battle just to be fought by people who need animal insulin, it is a battle in which we need all the support we can get. IDDT needs the support of the public, of your friends and your relatives. We are not asking for their money, but yes we're asking them to join us to fight the battle for the insulin we need. We're also asking them to fight an even bigger issue which could affect everyone in some way or another. We are asking them to support us to stem the tide of global multi-national pharmaceutical companies being able to dictate and control our health, our lives and our futures.

## We're not asking for a lot:

Diabetes may be complicated but our message to your friends and family is not.

We aren't asking for an expensive medication to be put on the market, we are asking for a medication to stay on the market, one that will certainly not cost the NHS more and in many cases cost less than the newer insulins.

## Ask your friends to use their imagination!

*Imagine you or your child having a lifelong condition that can only be successfully treated with one type of medication. Imagine a situation where that medication is denied to you or your child simply for money. What would you do? You'd fight tooth and nail for that medication, so please help us.*

In terms of decency and morality, the discontinuation of a perfectly safe medication that is essential to a significant number of people, simply does not stand up to scrutiny.

**Ask your friends and relatives to support you and IDDT by joining our supporters' list. Just send their names and addresses to Bev, Supporters, IDDT, PO Box 294, Northampton NN1 4XS or e-mail [supporters@iddtinternational.org](mailto:supporters@iddtinternational.org)**

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## Recent Cochrane Reviews

These regularly updated reviews look at randomised controlled studies on particular topics, assess their quality and draw conclusions from them to provide high quality evidence on which treatment choices can be made by both physicians and patients.

**Surgical versus non-surgical treatment for carpal tunnel syndrome  
July 2003**

Carpel tunnel syndrome is caused by the median nerve being trapped in the wrist [see IDDT Newsletter July 2003] and causes tingling, numbness and pain in the hand. Surgical treatment is widely preferred to non-surgical treatment for people who have significant symptoms but mild cases are usually not treated.

This review compared the effectiveness of surgical and non-surgical treatment with splints or corticosteroid injections. Only two small randomised controlled trials were found and the reviewer concluded that surgical treatment of carpel tunnel syndrome relieves symptoms significantly better than splinting but further research is necessary to discover whether this applies to people with mild symptoms.

### **Inhaled insulin instead of injected short-acting insulin appears no more effective for glycaemic control but may be preferred by people with diabetes July 2003**

Six trials have been done giving inhaled short-acting insulin before meals in conjunction with an injected basal insulin but much of the evidence from these trials has not yet been published in full. The results show that glycaemic control with inhaled insulin is comparable to that of people taking multiple daily injections and overall rates of hypoglycaemia appear to be similar. But the key benefits appear to be patient satisfaction, although again this information has not yet been published in full.

The reviewers say that it is too soon to know what the long-term effects on people's lungs are and that while inhaled insulin appears to be safe on the lungs, it will be 10 years before they can be confident about the long-term safety of inhaled insulin. Higher doses of inhaled insulin are required and this may make it less cost-effective than injected insulin.

#### **About the Cochrane Collaboration:**

To subscribe to the Cochrane Library visit [www.update-software.com](http://www.update-software.com) or contact Update Software [info@update.co.uk](mailto:info@update.co.uk) There is also a Cochrane Consumer Network that provides information and updates for consumers in easily understood, visit [www.cochraneconsumer.com](http://www.cochraneconsumer.com)

## **Novo Nordisk Name change For 'Human' Insulin**

Just to remind you that the Novo Nordisk range of synthetic human insulins are undergoing a name change - the word 'Human' will be omitted so that for example, what is now '**Human Actrapid**' will become simply '**Actrapid**'. The insulin products will remain the same and so there will be no need for a change of insulin type, dose or regime.

### **Important for Novo Nordisk pork insulin users!**

The names of **Pork Actrapid** and **Pork Insulatard** will NOT change but as the names are the same, IDDT has concerns that confusion or even errors could arise when a prescription for Novo Nordisk pork insulin is dispensed.

### **To ensure that GM insulin is not dispensed in error:**

- **ALWAYS** check that you have the correct insulin BEFORE leaving the pharmacy.
- **ALWAYS** read the Patient Information Leaflet even if you have been using insulin for years, because this is where any changes will be reported.

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## **Statins - The Anti-Cholesterol Drugs**

Statins are the group of drugs used to lower cholesterol. They are presently the most expensive item on the NHS drugs bill despite their recommended use being limited only to people who have a 30% chance of having a heart attack in the next 10 years. One million prescriptions are issued every month at a yearly cost of £440million. There is some evidence that increasing the use of statins could save more lives if they were more widely available. People with diabetes are at greater risk of heart disease and so are quite likely to be prescribed statins. Studies have shown that statin treatment cuts the risk of heart

attack and stroke and the evidence from a review in Bandolier [117, Nov 2003] suggests that they work as well in older people, over 65, as younger people under 65.

### **Statins may become over-the-counter drugs in 2004**

The patent is due to run out in 2004 and for some time it has been widely reported that Ministers will not block the application by drug companies to make statins more widely available ie over-the-counter [OTC] without prescription. In November, Health Secretary, John Reid, announced plans for a 9 week consultation period on the move towards OTC sales of statins. The proposal is that pharmacists should be able to supply the drug, Zocor Heart Pro, after simple on the spot health checks and the government wants a low-dosage to go on sale for about £5.00 a week. It would be available to people at both high and moderate risk of heart attack.

This is a significant step because up to now the only drugs available OTC have been for symptom control and not prevention or treatment. It could also affect a larger population as the intention is to make statins available to lower risk categories of people even though there is little evidence that statins are beneficial to people at low risk of cardiovascular disease.

Apart from the safety issues involved, this move also raises both political and practical issues:

- It shifts the health costs from society via the NHS to individuals, so would this mean that people who could not afford £5.00 a week be denied the preventative treatment? For a husband and wife the cost would be £10.00 a week.
- Surely pharmacists would need access to medical records in order to judge whether statins are necessary and advisable? How are they going to gain this access?
- What system would be in place for the the person's GP to be informed that the pharmacist has prescribed a statin?

But is making statin treatment available without prescription the best option for patients? Does it mean that people will pop a pill as the easy option in preference to trying diet and exercise with their many health benefits and without risking the adverse reactions associated with all drugs? Let's take a look...

### **Measurement of cholesterol levels**

A total serum cholesterol test measures the level of cholesterol in the blood to assess fat metabolism and the risk of heart disease. The cholesterol in the blood is made up of:

- LDL [bad] cholesterol ie low density lipoproteins
- HDL [good] cholesterol ie high density lipoproteins which have a protective effect on the heart
- Triglycerides which are the white fat that is eaten with meat and are also made in the body from other energy sources such as carbohydrates. Any calories consumed that are excess to requirements are converted to triglycerides and stored in fat cells. High levels of triglycerides in the blood may be a sign of poorly controlled diabetes.

Cholesterol levels are usually measured either as total cholesterol when the aim is that people achieve less than 5 mmols/l or are measured as levels of LDL when the aim is that this is less than 3 mmols/l.

**Note:** diet is responsible for only 25% of the total cholesterol levels, the body produces the rest.

### **Diet and exercise**

We are all aware that diet and exercise can reduce cholesterol levels, so diet and exercise is the first treatment and if this fails, then the use of statins may be recommended. Recent research in Canada [ Am J clin Nutr Sept 2003] comparing the effectiveness of lovastatin and a diet containing no animal products, no meat or dairy products, showed that this diet can reduce cholesterol levels as effectively as some of the latest and most expensive cholesterol-lowering drugs.

The range of foods eaten in the study included high fibre cereals such as oats and barley, soya products, fresh fruit and vegetables and almonds. This research demonstrates that people can improve their cholesterol levels without medication. It is worth noting that The Lancet [Vol 352: Oct 25 2003] says that the safety of statins cannot be assured, citing the withdrawal of Bayer's statin after unexpected deaths from rhabdomyolysis as the reason.

### **Like any other drug statins can cause adverse reactions**

Most of the statins on the market list similar adverse reactions - headaches, dizziness, gastro-intestinal upsets, myalgia and weakness. But only a couple of years ago, Bayer had to withdraw their statin from the market because of serious adverse effects. There are warnings [MIMS October 2003] that all statins may carry these same risks - muscle ache, reduced liver function and in extreme cases rhabdomyolysis [muscle wasting] and even total renal failure and these may occur particularly in people with renal impairment and hypothyroidism [under-active thyroid].

### **Statins are contra-indicated during pregnancy and breastfeeding**

This warning is associated with all statins and most of them including Zocor state: "Pregnancy: women must be protected by non-hormonal contraceptive methods".

Examination of the FDA surveillance records has identified clusters of congenital abnormalities in infants exposed to statins in utero. [Lancet. Vol 362, Nov 25 2003]

### **Claims of other benefits**

Laboratory studies have suggested that statins may have a favourable effect on bones and reduce osteoporosis but to date trials have had mixed results. A recent study [ref1] involving 93,000 postmenopausal women concluded that the use of a statin did not improve fracture risk or bone density and so the evidence does not warrant the use of statins to prevent osteoporosis.

There have been claims that statins protect against Alzheimer's but

the evidence is weak.

### **Can changing statins be harmful?**

It appears that the recommendation is that only one brand of statin is to be available OTC but if more become available, people may well change from one brand to another without knowing whether this is good or bad for them. Research in New Zealand [ref 2] has shown that changing statins can make matters worse. An audit was carried out of 126 patients who had changed their statin. Hospital records were examined for fasting lipids and hospital admissions for unstable angina, heart attacks, thrombotic stroke and peripheral artery occlusion for 6 months before and 6 months after the change from simvastatin to fluvastatin. The average dose of 22mg of simvastatin was changed to 37mg of fluvastatin. The change resulted in a significant rise in total cholesterol of 18%, LDL [bad] cholesterol by 34% and triglyceride by 13%. These significant increases occurred in 94% of people. There was also a threefold increase in total vascular events from 9 in the last 6 months on simvastatin to 27 in the first 6 months on fluvastatin.

### **Can stopping statins be harmful?**

Millions of people are taking statins but according to Bandolier [July 2003] even though they are prescribed by their doctors most people stop taking their statins after some time. If they become available OTC, it is not unreasonable to think that this is even more likely to happen.

A study [ref 3] of 3232 people who had chest pains, looked at the effects of stopping statins. 1151 patients had no statins at any time, 369 had statin treatment before their chest pain and continued with it afterwards and 86 people had statin treatment before the chest pain but this was discontinued at or after hospital admission with chest pain. The people on statin treatment had higher cholesterol levels after stopping it but the levels were still 10% lower than those who did not take a statin. However, the main difference was in the death rates and heart attacks in the 30 days after the onset of chest pain - these were lower in people who took a statin before and after the onset of chest pain. Those who had statins treatment withdrawn had

higher rates and not just higher than those continuing on statins but higher than those who were never treated with a statin, though not significantly so.

### **So can we draw any conclusions?**

John Reid says: *“People have the choice to give up smoking and to improve their diet, we want them to be able to choose a medicine that will reduce the risk of coronary heart disease.”*

Public health must not be put at risk by making statins an over-the-counter drug. We would remind Mr Reid that choice is no choice at all, unless it is an informed choice and this informed choice must include advice about diet and exercise. So it would seem that pharmacists will have to function as dietitian and doctor and be very vigilant in warning people about the proper use of statins, the possible adverse effects and the contra-indications.

Ref 1 Annals of Int Med;2003;139:97-104

Ref 2 Increased thrombotic vascular events after a change of statin. Lancet 1998 352:1830-1831 M Thomas, J Mann

Ref 3 Withdrawal of statins increases event rates in patients with acute coronary syndromes. Circulation 2002 105:1446-1452 C Heeschen et al

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## **Rae Price's Diary**

**In IDDT's October Newsletter Rae told us of her visit to the Professor to see whether she could have an insulin pump paid for by the NHS**

### **August**

I rang the Prof's secretary to see what was happening, after waiting

3 weeks to hear something I was getting a bit impatient. She said that the Prof had gone on holiday for 2 weeks but had written to the Medical something or other to see if the decision on who is going to fund this pump had been made.

This hot weather has been horrid as it has made the brittleness worse and my hands and feet are like balloons, but we shouldn't moan should we?

We are planning a holiday in New York and I'm a bit worried about time differences and the long travel time. We will be on the road and in the air for a total of 13 hours so Deep Vein Thrombosis and getting through American customs has to be the top of my priority list. The best web sites so far have been the USA customs site which lists exactly what you are allowed to take in and what you're not, in great detail and a site with Airline Aerobics to help stop DVT. It seems that they suggest you take 75mg of Aspirin a day for 3 days before you fly

### **22<sup>nd</sup> Sept**

After 8 weeks of waiting and 2 weeks spent speaking to answer machines I get the answer I wanted, yes I can have a pump funded by the NHS. Tomorrow I'm to have my normal (long + short acting) insulin in the morning then go to the Diabetes Care Centre.

By 11am I'm all plugged in and learning that a large Jacket Spud is now worth 60g of carbohydrate. I'm afraid I argued the point on this one as unless they now grow potatoes with more carbohydrate in than they used to, 60g is way too much! I kept repeating to the Diabetes Nurse that my long acting insulin would kick in on top of what I was now getting from the pump but it fell on deaf ears. At 11.30am the other diabetic attending who was having her pump changed over went hypo and drank a carton of orange juice - she said it was all that was needed. If only!! My last bad bout over the previous 9 days had had me taking the equivalent of 100g of carbohydrates at a time and promptly going hypo again 4hrs later.

This is something I had to see to believe and when going hypo that

afternoon, as I had predicted, I tried out the orange juice. Guess what? Yep a whole change of 0.2 from 2.3 to 2.5 wowiee as if I didn't guess that would happen!. So out came the usual chocolate bar and lucozade and half an hour later I went out for my tea. By the time I got there 5 minutes later I'm at 1.8 and the muscle contractions kick in just after I had managed to sink another glass of lucozade. I end up screaming (as usual when my jaw locks) and throwing about but still manage to say 'wait, wait' to my parents who want to call the paramedics. 10 minutes later something starts to work and half an hour later my levels are 12.6!

### **24<sup>th</sup> Sept**

Here we go with the swings and roundabouts again with this Novorapid stuff doing exactly what the other insulin's do and building up only to dump again 4 or 5hrs later. Up goes the basal rate (that's the rate that keeps you ticking over) and up goes the insulin the pump gives me immediately for each meal. So far we have swapped between 14.6 and 1.8 and 16.3 and 2.7. I'm told we should get a pattern over the next few days but to be honest after 5 years of this nightmare I find that very hard to believe. The major advantage is not having to stick a needle in when I need insulin and I gave the Diabetes nurse a HUGE grin when she said I only have to eat when I want to. Wow at last I will be able to go on a diet and loose all this excess flab.

### **27<sup>th</sup> Sept**

It's been difficult persuading my parents that they can cut any portions they give me in half and that I don't have to have something to eat every 3hrs. The difference in how and when food/lucozade kicks in has been the most dramatic change so far. I don't need to pile up the calories or carbohydrates when I'm hypo anymore I can get away with 2 biscuits or a small glass of lucozade not a whole bottle. Fingers crossed it will give me a waistline back.

### **30<sup>th</sup> Sept**

The insulin I'm having with my meals is kicking in 3hrs late but can I actually get this across to the Diabetes Care Nurse? Nope, but I am following, to the letter, everything she is telling me to do otherwise I

might get accused of doing something wrong on purpose. The really nice thing is getting back the hypo warning signs and I'm now starting to feel low at 3.3. The swings and roundabouts are getting worse not better but you never know we might get there eventually. I'm really looking forward to the IDDT AGM as they have a hypo expert talking and it will be "Come here, pet, lets talk." My bad moods are back and the fuse has become rather short on my temper again. I'm afraid everyone in the local vicinity has had their heads snapped off including my parents and the x. This isn't really like me at all and I haven't had this problem since I was last on the synthetic 'plastic' insulin but I did promise I would try this for 6 months so here goes.

### **8<sup>th</sup> Oct**

The swings and roundabouts have settled down at last and we actually seem to be getting a pattern. Fine adjustment is very easy with the pump but a 0.1 change per hour does make a quite a difference. I seem to have got the basal rate near enough right and the insulin I am taking with meals is cutting in quicker which is nice.

### **15<sup>th</sup> Oct**

The AGM was wonderful and I learned loads including that my muscle spasms are called seizures. This I found utterly horrifying at first but eventually realised that of course they're seizures as the brain is misfiring, so it's not worth getting freaky about. I also realised how different we all are in the way we handle and control our diabetes and what suits one person may not necessarily suit another. So far this pump is the only thing that has given me fairly steady control but someone else might find it far too fiddly and cumbersome.

I'm now starting to suffer from all the usual side effects of synthetic insulin again including major fatigue, skin fungal infections and irritability. When I know I'm really snappy I try to make sure I am on my own so no one else suffers, its difficult though, especially when you have to keep counting to 10. My hands are swelling up again and I've got a nasty tooth abscess but these things are sent to try us and it's only three and half months to go.

## IDDT Messages

### Thank you!

Many thanks to everyone who has supported IDDT by buying Christmas Cards - we very much appreciate your help.

### Apologies!

In September the Post Office Sorting Office in Northampton was attacked by vandals and 25% of the mail was burned followed by weeks of delayed deliveries and collections. If you wrote to us during this time and have not received a reply, we can only apologise. Please do get in touch with us again. We also have to apologise for our website being down for a few days and difficulties with our e-mail service - these have been due to problems beyond our control.

### Annual Meeting 2003 and 2004!

The meeting was well attended and lively! Thanks to everyone for the flowers - they were beautiful. A report of the meeting will appear in the next Newsletter as neither time nor space allowed for it in this edition. The discussion groups proved very useful as they were asked to discuss what IDDT should do in its 10th Anniversary year. The messages were clear:

2004 must be the year that we expand our activities to reach people with diabetes to share knowledge and information with them. IDDT has to become the *'Voice for Choice'*!

Above all, everyone wanted a one-day celebration conference to reach out not just to members, but to the other people who do not know about IDDT. There were some brilliant ideas - just what happens when people are 'locked' in a room together! We may not be able to fulfil these high hopes but we will certainly do our best. The provisional date for your diary is Saturday, October 9th 2004!

### Clarification needed! IDDT has no vested interests

Over the years some not too nice things have been said about IDDT - the maverick organisation! Recently one of our members, trying

to change to animal insulin with some of our literature in her hand, was told by a professional that IDDT and some of the Trustees have a vested interest in animal insulin sales. Other people have made similar, and even worse, implications, so it is important that the position is made absolutely clear.

IDDT receives absolutely NO funding from any part of the pharmaceutical industry and neither IDDT nor any of the Trustees have a vested interest in animal insulin sales, ie no financial gain. Our only vested interest is to ensure that people know it is available and remains available for those who need it. All IDDT's funding is from voluntary donations. Copies of the full audited accounts are available to anyone, just call IDDT on 01604 622837 or e-mail [bev@iddtinternational.org](mailto:bev@iddtinternational.org)

### Pregnancy Leaflet

We receive quite a lot of calls about pregnancy and breastfeeding and the next Newsletter will contain an article that we hope will help. In the meantime we have a new leaflet on Pregnancy and Diabetes. All our leaflets are free just contact

**IDDT, PO Box 294, Northampton. Tel 01604 622837 or e-mail [leaflets@iddtinternational.org](mailto:leaflets@iddtinternational.org)**

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## Updates From October 2003 Newsletter

- **Target Tales**

**Relaxation of 4 hours in A&E** - the A&E targets set by the government are that all A&E patients have to be dealt with in 4 hours but the Dept of Health has proposed the creation of 'clinical exceptions' which will be exempt from the 4 hour target. This would include people who need to be monitored for longer than 4 hours or where their condition deteriorates and it would be unsafe to move them to a ward. According

to the DoH the target is not being abandoned but excludes some patients for clinical safety reasons.

**Hospital infections** - the government has given hospital pharmacists £12million over 3 years to monitor how doctors use antibiotics. It is thought that a key factor in the rise in resistant bugs found in hospitals could be the overuse of common antibiotics. There will also be an extension of the current reporting scheme in an attempt to find out how infections are transferred from person to person. Hospitals will have to tell the Health Protection Agency every time they have an infection that is resistant to a key antibiotic family and report any serious incidents such as closure of a ward due to an outbreak of vomiting. Dr Liam Fox, Shadow Health Secretary, told the BBC that 'Simple rules of hygiene rather than doling out packets of money is what the focus should really be on'.

**Surgery waiting lists** - Dept of Health figures show that between April and June 2003 over 14,000 people in England had surgery cancelled just days before, for non-clinical reasons. In addition, many hospitals trusts were still failing to admit many of these patients within 28 days, as promised. The Audit Commission found that many operations are cancelled for lack of staff or because theatres are already too busy. £8.5million was allocated to this problem last year and a further £7.4million is to be spent this year.

- **The bee in my bonnet - Avandia and Actos**

Regular readers know that I have a bee in my bonnet about Avandia and Actos which are insulin sensitisers from the glitazone family of drugs for Type 2 diabetes. They may lead to serious side effects of cardiac and liver complications. There is yet more research:

- Research presented at the Northern Menopause Society [Abstract S4] indicates that Avandia may not be as effective when used in women taking HRT.
- Research into Avandia [Endocrinology 18.9.03] suggests that its use results in significant bone loss so that it may pose a significant

risk of adverse skeletal effects, such as osteoporosis.

- Clinical Proceedings 9.11.03 confirms that both Avandia and Actos can cause congestive heart failure and pulmonary oedema. The researchers noted that they are being prescribed for people with renal insufficiency because metformin is not recommended for them but this new research suggests that this group may be at a high risk of developing heart failure. They recommend that additional research needs to be done to identify the different groups of people that may be at risk of these complications.



## From Our Own Correspondents

### Does anyone else have problems with Medisense G2 sensors?

Dear Jenny,

Having successfully used Medisense blood sugar sensors for many years I am exasperated by the new G2 sensors, very recently released.

The previous ones required very little blood to operate, which could be placed anywhere on the calibration band. The new ones require lots of blood and laser accuracy. I have lost count of the number of strips wasted and the number of failed attempts to read my blood sugar.

Have any other people with diabetes suffered similar problems? Can Medisense be made to revert to the old strips which were far easier to use, particularly by older diabetics. I have written to Medisense and await a response.

Mr JB  
South East

Dear Jenny,

Awaiting the pump I decided to see whether any of my present difficulties could be ameliorated by a switch back to pork insulin. Whilst it isn't a miracle cure it certainly seems to be helping. It's like a Ronseal woodcare product, it does what it says on the leaflet. If hypos happen then they are at a predictable time for me - 1.75 hours after injection.

Mrs EJ  
North West

### **What a difference in his behaviour**

Dear Jenny,

Earlier in the year, I contacted you about my 10 year old grandson and the problems we were having with his behaviour both at school and at home since his diabetic diagnosis in January 2002. We talked to his consultant and nursing team about changing to animal insulin and they did consult your website. Eventually they agreed that my grandson could be given pork insulin instead of GM.

For the first two weeks it appeared to make little difference but since then there has been a dramatic change. His class teacher says his behaviour has improved so much that he's now helpful, polite and working really hard in an attempt to catch up with his work. His diabetic control is a lot better and he doesn't have any sudden hypo's anymore although his blood sugars sometimes do go low but he does have adequate warnings whereas before he had none.

I think some doctors are now accepting that GM insulin is not for everyone. I have Type 2 diabetes and six weeks ago I went into hospital for an operation and I told the doctors that should my diabetes get worse during the operation, I did not want to be given GM insulin. I was given a red warning bracelet which said that I should only be given porcine insulin. I did need insulin for two days and my request was granted. Perhaps your message is getting home!

Thank you for the information we've had from your organisation, I think we would have had difficulty without it.

Mrs VJ  
North East

### **I was slowly dying**

Thanks for the email Jenny.

I am a diabetic and have been on insulin for 23 years since I was 3 years old. Yesterday I successfully got my good old MIXTARD porcine back, much to the disgust of my consultant.

In my teens I was put on to Human Mixtard 30/70, then put on Human Actrapid before meals and Monotard ( human at night). Then was switched to Humalog with Human lente at night and then the AWFUL glargine (Lantus) with Humalog.

For years I have been ill with bouncing blood glucoses and always being fobbed off and labelled a brittle controlled diabetic. I have now developed retinopathy (I am having surgery shortly) and neuropathy which I am successfully controlling with 600mg of Lipoic acid every day. For years I felt I was, to put it bluntly dying, but I managed to scrap through university though, as I am a determined little thing.

A month ago I demanded that I was put back onto Human Mixtard at least. Within 3 days I felt alive with blood glucoses being between 3.8 and 9.9 mmol/l which for me is amazing and a lot better than the 2 to 22 mmol/l I have been experiencing. When I received your info my husband and I decided that I request the Porcine Mixtard, my GP is great and said of course. My pharmacist is trying to get hold of it and I should receive it tomorrow. My consultant will turn blue and breath smoke but it is my life and my GP agrees with me.

Keep up the good work! I am a loyal supporter and will let you know how I am doing on the porcine.

Kindest regards and thanks for changing my life

Lucy Brazier  
Midlands

### **Don't forget PZI**

Dear Jenny,

It was most interesting to read patients' good and bad reviews of Lantus insulin, July 2003 Newsletter. I am surprised that people are encouraged to go on this long-acting GM insulin when there is a long-acting and in my view superior insulin available - Protomine Zinc [PZI] beef insulin.

I have been on this insulin for the last 25 years and it has saved me a third injection at bedtime. [I am needle shy even after 40 years of diabetes.] I mix PZI with Neutral insulin before my evening meal, despite CP Pharmaceuticals warning against mixing PZI and Hypurin Bovine Neutral in the same syringe because the PZI can bind with the soluble neutral insulin and can therefore alter the time action of the soluble insulin. However, this has never been a problem for me. It is yet another insulin and regime that may help other people and I wish that consultants and GPs would recognise this as yet another choice for people. PZI also has the advantage of being a cloudy insulin and therefore cannot be mistaken for clear short-acting insulins, as could happen with the clear long-acting Lantus.

PZI has been a 'life-saver' for me, enabling me to stay on two injections a day and I would be interested to know if any other readers use it and mix it with short-acting insulin and if so which ones. The Diabetes Nurse tells me that she doesn't think PZI will remain available for much longer, despite recent assurances to the contrary from CP Pharmaceuticals. I find this very worrying as my HbA1cs are always around 6.3 to 6.5. On PZI I can have a lie in at the weekends [without any undue rise in my blood sugars] as PZI lasts until mid-morning. I am sure that other people with diabetes who need long-acting insulin would find it extremely beneficial.

Mrs E.B.  
Yorkshire

**IDDT Comment:** We have checked with the manufacturer of PZI, CP Pharmaceuticals, and they have NO plans to discontinue any of their beef or pork insulins, including PZI, so do not believe the rumours about the future of CP animal insulins.

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## **Perhaps We Should Know A Little More About Cystitis**

### **Bacterial cystitis**

Many people experience cystitis, the common form called bacterial cystitis which is a urinary tract infection caused by bacteria. It is usually treated with antibiotics and attacks tend to be short and only last for a few days. Although more women than men are affected, it can affect both men and women. Bacterial cystitis attacks tend to be short and last for only a few days.

### **Interstitial cystitis [IC]**

This is chronic inflammation of the of the bladder wall, the symptoms are not relieved by antibiotics as the cause is not thought to be bacterial. The symptoms tend to be continuous and permanent - pain and discomfort with the bladder filling with temporary relief during voiding.

IC affects people in many different ways with no one set of symptoms but many people with IC say that their life revolves around finding the nearest toilet. Some people are so badly affected that they are almost housebound and many feel tired as a result of having to get up frequently during the night. Pain can be permanent and this can affect relationships at home or at work.

## Trigger foods

A large number of people find that certain foods and drink can aggravate the condition. These are usually foods or drinks that are high in acids such as some cheeses, yoghurt, most fruits and juices, onions, tomatoes, most nuts and processed and smoked meats and fish. Certain chemicals and amino acids can also irritate the bladder lining and included in this list are artificial sweeteners! As everyone is different, it is important to find the trigger foods and the Interstitial Cystitis Support Group have advice on how to try to do this and they also have other useful information.

Their details are as follows

Interstitial Cystitis Support Group,  
76 High Street, Stony Stratford, Bucks MK11 1AH  
Telephone/Fax 01908 569169  
E-mail [info@interstitialcystitis.co.uk](mailto:info@interstitialcystitis.co.uk)

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## IDDT's Roving Reporter

### Lorraine Hill, Canada

For almost forty years, I've read of the great work being done by diabetic charitable groups. Where has the money gone? This is the first in personally rating the non-profit diabetes groups.

We all are familiar with the large, sombre brochures, usually with an aging couple on the front: annual reports. Most are tossed into the recycle bin, but the Canadian Diabetes Association's [CDA] report holds a special attraction to me. Most of us have pledged, walked, ran and sweated in some form to contribute to charitable donations, and where the heck is the cure? My values may be twisted, but I don't care if the financial statement comes on 24-lb paper, or the report on tasteful tri-colour glossy print. I want a cure.

The CDA's summary financial statement for last year states

\$5,353,000 towards research. That sounds impressive, until you read that operations cost \$18,432,000.

That does not include general administrations. Add another \$6,496,000. Fundraising cost: an additional \$13,944,000. Those t-shirts and baseball caps do not come cheaply. Throw in communications, government programs and that 'other' category for a whopping \$56,829,000.

Over \$56 million goes to administer a non-profit group that is shovelling out a miserly \$5.3 million for research? Less than 9 per cent of their expenses. Not good enough.

I've received better, more concise information from this newsletter, than in the forty years of 'service' the CDA has given me.

**My rating of CDA: 4 out of 10**

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## News For Visually Impaired people

### A talking blood glucose meter but...

The need for people with visual impairment to monitor their own blood sugars is vital if they are to achieve optimal diabetic control with a minimum of hypos and maintain their independence. So there is a very real need for a blood glucose meter with a voice synthesiser that 'speaks' the results. These 'talking' meters were withdrawn from the UK because there was only a small market!

One of our visually impaired members has discovered a talking meter that works very satisfactorily for him. It is called the Gluki Plus and requires only a very small sample of blood and after 30 seconds the test results are announced in a clear voice. However, there is a very big BUT - the cost! It is £430 and the additional packets of 50 sensors cost £22.30 - a cost most of this very vulnerable group will not be able

to afford.

IDDT has raised this issue with government bodies and while individuals within those bodies are always very sympathetic, no one takes responsibility or is able to offer any assistance.

**Further details can be obtained from:**

**Vis-Ability [DK], 211, Creek Road, March, Cambs PE15 8RY Tel 01354 656560**

**Website [www.vis-ability.co.uk](http://www.vis-ability.co.uk)**

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## Bits And Pieces

### **National Toilet Card launched to help people who have to rush to the toilet.**

The card is credit card size and can be shown to staff in high street shops and businesses to ask to use their facilities or to find out where the nearest public toilets are. The card has been produced as part of the Healthy Bladder Campaign run by InContact and supported by 21 related organisations. For more information about the card call InContact on 0870 7703246, e-mail [info@incontact.org](mailto:info@incontact.org) or visit their website [www.incontact.org](http://www.incontact.org)

**New advice on the possible harmful effects of vitamin and mineral supplements.** This advice comes from the Food Standards Agency [FSA] following an independent report. The amounts of most vitamin and mineral supplements are not thought to be harmful but some may have harmful effects if taken in large doses over a long time. These include beta-carotene, nicotinic acid, manganese, phosphorus and zinc. Doses of Vitamin C above 1000mg, calcium above 1500mg and iron above 17mg per day can cause abdominal pain and diarrhoea which will disappear after ceasing to take them. Further information is available from the FSA website [www.foodstandards.gov.uk](http://www.foodstandards.gov.uk)

Artificial blood used for the first time - researchers in the US have developed synthetic blood which comes in powder form so that it just needs to be mixed into liquid form. It can be used quickly when needed regardless of the patient's blood type and it has also been shown to transport oxygen around the body better than normal blood. The exact process for developing synthetic blood has been kept secret but it is made from human red blood cells although researchers say that it could just as easily be made from any mammal. It has been tested for the first time on 8 patients.

### **European Evaluation of Medicinal Products - patients' working group**

This is a new group which met for the first time in May 2003. It brings together members of the Committee for Proprietary Medicinal Products [CPMP] and representatives of European patients' and consumer organisations. It was created to bring patients closer to the regulatory process for medicines and will focus on three main areas:

- transparency and dissemination of information
- product information for medicines
- pharmacovigilance [monitoring of drugs and adverse reactions once on the market]

This has got to be in the interests of patients!

### **New guidelines for nurses on administering IV drips, October 2003**

The Royal College of Nursing Report says that patients are being put at risk of infection and discomfort because many nurses are not using intravenous drips properly by using the wrong equipment or by not changing it often enough. It also says that standards can vary in the same hospital and even in the same ward with some changing the cannula or tube every 3 days as recommended while others change it only once a week. The RCN wants these guidelines implemented with urgency.

**Monkeys lose 7% of their body weight - a new hormone-like**

compound tested on monkeys resulted in 7% of their body weight being lost in a week. It works on the same principle as the hormone produced by the thyroid - weight loss occurs by boosting the metabolic rate so that the body burns off more calories. So the drawback is that it causes a potentially fatal increase in heart rate. Scientists hope that they can separate these two effects, the perhaps produce a drug that would produce the weight loss without the heart problems. [Eat less sounds a much better option!]

### **Problems with xenotransplantation are being overcome.**

Xenotransplantation is tissue transplantation across species ie animal-to-human transplantation of organs. It is hoped that this would solve the world shortage of organs for transplantation in conditions such as diabetes. The main barriers for this are rejection of organs and cross species infections but researchers at Glasgow University working with colleagues in the US think that they have overcome the rejection problem by breeding pigs that have been genetically modified to eliminate the rejection problems.

### **Obtaining cannabis illegally to treat painful diabetic neuropathy.**

The South London Press [12.9.03] covered the story of a man with diabetes and extremely painful diabetic neuropathy. He has been prescribed large numbers of drugs, with some of them being prescribed to counteract the side effects of the others. He finds smoking cannabis [illegally] gives him relief without all the side effects caused by the prescribed drugs. We have read about this for other painful conditions - not something we normally associate with diabetes, but pain is pain. The Dutch government changed legislation so that from September 2003, cannabis could be dispensed to people with a doctor's prescription. The UK government is already considering an application to use cannabis in medicines and no doubt will be closely watching the situation in Holland

### **More bodybuilders using insulin**

Researchers at Hull Royal Infirmary have found that the number of bodybuilders using insulin to enhance their performance is increasing despite the potentially fatal consequences. Insulin increases muscle

bulk and is often used in combination with anabolic steroids. In a recent case reported in the British Journal of Sports Medicine, a man found unconscious in his home was admitted to hospital and treated for hypoglycaemia. Doctors assumed he had diabetes but it turned out that he was a bodybuilder who admitted to taking insulin 3 times a week but on this occasion he had taken fast-acting insulin instead. [The temptation is to say that it served him right!]

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## **Drug Alert Scheme 'Deeply Flawed'**

This is the headline in a report by the BBC [21.11.03] and refers to the Yellow Card Scheme - the UK system designed to highlight side effects of medicines. Doctors, some health professionals, coroners and the drug companies themselves are expected to report any suspected adverse effects of medicines on a Yellow Card to the Medicines and Healthcare Products Regulatory Agency [MHRA], the new name for the Medicines Control Agency [MCA].

Regular readers will know that IDDT has been critical of the system for two main reasons:

1. It relies on professionals to make the reports and it has long been estimated that there is gross under-reporting with only 10% of adverse reactions being reported.
2. It does not allow patients or their carers to report adverse reactions directly to the MHRA so they have to rely on doctors/health professionals believing them and then actually sending in a report.

Panorama covered the adverse effects of the antidepressant Seroxat which has caused widespread concerns as it has caused some people to have suicidal feelings. The BBC received hundreds of letters and e-mails from patients or their families and these were analysed by Dr Andrew Herxheimer, Oxford University, and Dr Charles Medawar from Social Audit. They also examined 1000 Yellow Card MHRA

reports about Seroxat. While they found that many Yellow Cards contained details that might raise suspicion that Seroxat was involved in suicidal thoughts or behaviour, the reports were often classified into different headings, lessening their impact, and some side effects were completely wrongly labeled.

According to Dr Herxheimer the findings through into question the value of the Yellow Card Scheme and he questioned whether the data it produced could effectively highlight adverse effects in a timely way. He described it as 'chaotic and misconceived'.

In contrast the analysis of the patients reports to the BBC suggested that far more useful information could be obtained if, as in other countries, patients were encouraged to send details of side effects rather than doctors or pharmacists.

**The Scheme is currently under review by the Department of Health.** A spokesman said there are other ways that problems with drugs could come to light but did add that patients' experiences can make an important contribution. She said that a pilot scheme enabling patients to report adverse reactions through NHS Direct is currently being evaluated. Amazing that she does not realise that this is NOT patients reporting adverse reactions, it is patients reporting them to a nurse who then decides whether or not to report them to the MHRA! Patient reporting means that patients report directly to the regulatory body as happens in other countries.

### **Why does this matter to us?**

It matters because the purpose of the Yellow Card Scheme is to offer the public protection by quickly alerting the MHRA if a drug is suspected of causing adverse reactions.

As synthetic 'human' insulin was introduced without scientific evidence of benefit and good quality studies comparing animal and 'human' insulin have never been done, the Yellow Card Scheme reports should provide valuable evidence. We know that there is a 90% underreporting of adverse reactions for drugs but as doctors

have not believed us when reporting adverse effects with synthetic insulins, this underreporting could be even higher. In addition to this Dr Herxheimer's findings suggest that reports that have been made could be lost in what he describes as 'the chaotic and misconceived system'. Thus Yellow Card reports collected for synthetic GM insulins are by no means a true reflection of the reality and do not offer the protection or the warnings that we, and prescribing doctors, need. This is why it matters!

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## **What The Papers Say**

**GlucoWatch manufacturers reduce workforce** - the GlucoWatch Biographer is the glucose monitoring device that looks like a watch and monitors blood glucose levels non-invasively ie without taking blood. It is not sufficiently accurate to replace finger prick blood glucose testing, although it can provide a better overall picture of blood sugars over 24 hours. It has not been advertised in the UK now for some time and on October 9th 2003 the manufacturers, Cygnus, announced that they had reduced their workforce by 60%. It appears that Sankyo, a Japanese company with a base in the US, who market the GlucoWatch have decided to cease marketing and distributing it. Legal action is taking place.

**Aventis expect sales of Lantus to continue to grow, October 2003** - with sales of over 2 billion euros in the first half of 2003, Aventis report that they expect that this will grow significantly in 2004. They now have two plants producing Lantus and have applied for EU and USA approval for a new short-acting insulin, Apidra.

**Aventis launch Lantus in India, July 2003** - according to the press release the launch of Lantus in India reflects Aventis' commitment to bringing the latest bio-technological breakthrough in a speedy manner to the Indian population. Just so happens that India has the largest diabetic population in the world, 37 million people with this estimated

to reach 57 million by 2025. Lantus will be available at an introductory price of Rs2,499.

**New Research Centre opened in Oxford, September 2003** – at the official opening of this new Research Centre, Prof David Matthews said he was confident that scientists would stamp out diabetes by 2015 and the Centre in Oxford will play a leading role in this. The Centre is the first to integrate research and treatment under one roof and cost £11 million, £4 million from Novo Nordisk and £3.2 million from Japanese drug company Takeda. [If Professor Matthews is correct, the generous donations of these companies will do them out of business.]

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## Information About The Medicines We Take

If you have access to the internet then the electronic Medicines Compendium [eMC] provides free access to information about prescription and over-the-counter medicines in the UK.

For medicines to be prescribed or sold in the UK they have to be approved by the Medicines and Healthcare products Regulatory Agency [MHRA] and this approval is based on information about a medicine's effectiveness and safety. Two of these documents are available to the public and they are:

- Summary of Product Characteristics [SPC] which gives the properties, effects and warnings about a medicine and they are written to guide healthcare professionals on its use.
- Patient Information Leaflets [PIL] which is the leaflet for patients included in the medicine packaging.

Both these documents are available on the electronic Medicines Compendium so patients have free access to the SPC for healthcare professionals as well as the PIL. To find this information visit [www.medicines.org.uk](http://www.medicines.org.uk)

[medicines.org.uk](http://www.medicines.org.uk)

The eMC is funded by the pharmaceutical industry.

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## Snippets

**Nobel Prize winner says more money should be invested in health education rather than designing genetically tailored drugs.** Professor Sydney Brenner told the BBC [2.9.03] "Everything is being driven into the support of the pharmaceutical industry. There's two kinds of health care. There's taking care of the health of the public and there's taking care of the financial health of drug companies." He suggests that we need a new appraisal of the relationship between these things.

**Consultants writing to patients?** Health Secretary John Reid has indicated that he wants to look at changing the way that doctors' and patients' correspondence is handled. The new idea is that consultants will write directly to patients, rather than writing letters to GPs which are then copied to patients. The idea will be explored with patients and clinicians.

**Hospitals send doctors and nurses on courses to learn how to write better patient notes!** This is part of a move to reduce the £4.4 billion NHS clinical negligence bill. Experts believe that many of these claims could be defeated if medical staff kept proper notes. Some hospitals lose cases because staff fail to include such basic information as the time that procedures are carried out and the use of acronyms not understood by other staff. In one incident an A&E doctor told a patient's family that she had died because the doctor thought the acronym DOA meant 'dead on arrival' when it was meant to mean 'date of admission'. One company trains thousands of NHS staff each year to write better patient notes but dare we ask who's paying for this? No doubt our strapped for cash NHS!

**Guinness is good for you after all!** Many years ago Guinness were told to stop using the old advertising slogan 'Guinness is Good for You' but perhaps it should be brought back. Researchers at Wisconsin University have found that a pint a day can reduce the risk of heart attacks. The researchers say that it works as well as aspirin in preventing blood clots that can lead to heart attack. They tested the health-giving properties of Guinness against lager by giving it to dogs with narrowed arteries and found that dogs given Guinness had less clotting in their blood than those given lager!

**Charities can't retain staff despite an increase of 6.1% in salaries!** A survey carried out for the National Council for Voluntary Organisations has revealed 55% of voluntary organisations reported problems retaining staff compared with 41% last year with staff turnover also increasing. These problems have arisen despite an overall increase in salaries of 6.1%, an improvement on the 4.7% last year. By comparison chief executives salaries increased by 8.5%.

**And by the way...**

### **New Prescribing Powers For Designated Health Professionals**

Specially trained healthcare professionals, to include community pharmacists and nurses, will be able to prescribe some medicines to certain groups of patients under specified circumstances and using an agreed management plan. For this to happen, there has to be a Patient Group Directive [PGD], a written authorisation document to the healthcare professionals and the doctor will have to sign an agreed plan for each patient. Diabetes specialist nurses will be able to train to be able to supplementary prescribe within an agreed management plan but will not be unable to independently prescribe the majority of medications and treatments for diabetes. Patients will have to pay the normal prescription charge unless they are exempt.

**Xenical [orlistat]**, the anti-obesity drug made by Roche, is in the latest list of drugs to be made available under this PGD system. Trained community pharmacists will be able to supply Xenical directly to patients without a doctor's prescription if this is within weight

management clinics. New information about Xenical has been added to the datasheet. It now says that with the drug, weight reductions are less in people with Type 2 diabetes than in people without diabetes and also that anti-diabetic treatment may have to be closely monitored when taking Xenical.

**Note:** A campaign that was run in Scotland last year offering information on 'better health and weight loss success' has the makers of Xenical, Roche, logo on it but advertising of prescription drugs is illegal! While the campaign may be about treatment awareness, the reality is that it is actually advertising Xenical for Roche!

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

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## From Your Editor – Jenny Hirst

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