Registered Charity No 1058284 - Issue No 30

Insulin Dependent Diabetes Trust

October 2001 Newsletter

Be Kind To Yourself!

But perhaps we should add – and to others!
By Jenny Hirst

This was a message given to me by a good friend many years ago when my life seemed a bit difficult, for one reason or another. She was giving me permission to allow me to feel sorry for myself occasionally and not to always feel a failure if I didn't always achieve what was expected of me. It was a good message and one that I remember when things are difficult. Perhaps it is a good message for many of us, because life is not always easy and we don't always cope with some of the difficulties that arise - sometimes we cope better than others but perhaps we also need to remember that some of us cope better than others.

Reading the letters page of a well-known diabetes magazine was quite an eye-opener. A letter appeared from a man who was quite bitter and fed up at having been diagnosed with diabetes. [We all remember how that feels!] The responses in the next edition were unkind, albeit perhaps unintentionally. Virtually two pages were given to critical letters of the man who was finding life difficult, accusing him and others like him, of being 'whingers and a whiners' and that 'nobody said life was either fair or easy, so live with it!'

These responses to this poor man were from people with diabetes which raises the obvious question. If people with diabetes do not understand each other and have some sympathy for those who find life difficult, then how on earth can we expect people without diabetes to understand or even sympathise from time to time? How many times do we complain that our doctors, healthcare professionals and the general public do not understand what it is like to live with diabetes?

Yet here we have this poor man berated by other people with diabetes for having, what sometimes is a justifiable, grumble about life. It shows a lack of care and understanding that life with diabetes and its complications can be difficult and even disabling. Anyway, aren't we all entitled to a grumble every now and then?

Two images of diabetes

Diabetes has two images. First, the image of life with diabetes that is all too often painted, one of fit and healthy people that apparently sail through life, climb mountains and do all sorts of daring things and their diabetes does not appear to cause a problem. Usually the underlying message is that if you look after yourself properly, then you too can have this good life! [So it's your fault if any complications occur!]

The second image of diabetes rather contradicts this and is used when trying to raise funds for research. Then the picture is quite different and the image of diabetes is painted as the awful complications to illicit sympathy to raise funds to help 'these poor people with diabetes'!

Yes, it is quite possible to paint a good picture of life with diabetes and most people experience this good life for many years. But if life with diabetes was really like this for everyone, then the NHS would not need to be spending as much as it does on diabetes care! If we forget or ignore the reality, then we are in danger of showing as little sympathy and understanding to those of us that are not coping too well when life is tough, as the authors of the critical letters.

There must be a middle road

I don't need to spell out the reality of the complications - the daily fight against hypoglycaemia especially with loss of warnings, the prevalence of heart disease in people with diabetes, that diabetic retinopathy is still the largest single cause of blindness in the working population, the pain that neuropathy can cause or facing life with kidney damage. These can be the effects of having diabetes and many of them occur as a result of having diabetes for a long time. Surely we should all recognise that there are stages of diabetes, not two extreme ends of a spectrum and this is the middle road that we should tread. This way we can see that the effects of diabetes are different in all of us and we are all individuals so how we deal with them differs - our lives are different, some people live alone and some have a lot of family support. But none of us in this situation are 'whingers and whiners', we are people faced with diabetes and/or its complications.

Just coming to terms with the diagnosis of diabetes is not easy and coming to terms with the complications can be just as difficult, especially if this means major changes in our lives, such as stopping driving or retirement from work. So from time to time it is not unreasonable that we should want or need a grumble, that we should feel upset or angry at the blow that has been dealt to us. Sometimes we should allow ourselves this touch of self-indulgence and that was my friend's message all those years ago – be kind to yourself!

As a parent of someone now entering the next stage of diabetes with some of the complications occurring, I have felt upset and disappointed for her. I have tried to support her whenever possible but I have felt once again the guilt of motherhood and wondered if I could have done things better so that the complications would have been delayed. Perhaps I have been a 'whinger and whiner' sometimes but unlike when she was diagnosed 26 years ago, this time I have allowed myself to experience these feelings and come to terms with the new situation in my own time. I have been kind to myself and I hope, to my daughter in the process.

Private Sector Funding In The NHS

Almost immediately after the election campaigning began Tony Blair suddenly announced that there would be 'no ideological bar' of the wider use of private companies in the NHS. In 1997 Labour pledged to save the NHS from the results of the previous government's internal market. So this announcement came as a surprise to Labour supporters who don't forget that it was a Labour government that introduced the

NHS in 1948, and to many others that have reservations about public/private partnership in the provision of healthcare.

Mr Blair suggests that it is ideological beliefs that are responsible for the expressed opposition to public/private partnership in the NHS. Yes, there will be people who oppose it on ideological grounds but there are many others who are concerned about the expansion of the public sector's role in reforms of the NHS. The Institute for Public Policy Research has issued a report that rejected the idea that public/private partnerships in health have provided value for money nor was there any evidence that private money had created any extra cash with little evidence of any resulting innovations.

In the face of the rising opposition, the government does not seem to have a clear plan of what it means, or if they have this is certainly not coming across to the public. At the time of writing this article, Alan Milburn had set out four areas where private and voluntary sector involvement could be expanded:

- the new 24hour fast track surgery units
- using the private sector's spare capacity to reduce waiting lists
- expansion of private funding to encompass GP premises, mental health and social service facilities
- running IT systems and NHS buildings.

Whatever the outcome, it looks increasingly more difficult for the government to deliver the July 2000 health plan that was endorsed by 24 of the country's leaders in medicine, nursing and management. Did they know of the government's intentions to use public/private partnerships when they endorsed the plan, we wonder?

Creeping privatisation coming in through the backdoor.
We only have to look in our own back yard to see that pharmaceutical industry funds parts of the NHS that once would never have happened - diabetes centres that are partly funded by them, both building costs and staff salaries. The salaries of some diabetes specialist nurses are also paid by them to say nothing of funding for necessary equipment for our treatment.

Here is just one recent example of industry funding that could well be classed as a minor part of public/private partnership:

Register of diabetic patients - Highland region in Scotland has announced that there is to be an area-wide register of people with diabetes to the obvious benefit of people with diabetes in the area. Highland Health Board has also created the appointment for a Diabetes Facilitator to plan and improve services – the post will be part funded for 3 years by Pfizer Ltd, the pharmaceutical company. They are also going to appoint a clinic administrator on a 4month pilot basis with the aim of providing a more personal service for patients - £5000 being given by another pharmaceutical company, Inverness Medical Ltd, now Johnson and Johnson the manufacturer of Lifescan blood glucose meters.

There is no doubt that these sorts of initiatives will improve the standards of care we receive but in the case of a register, patients need to be assured first and foremost, that it will remain entirely confidential and it will not be used to advertise the diabetes products of these two companies, either directly or indirectly.

So does it matter where the funds come from as long as we receive better care? Maybe not but we have to remember that private enterprise is all about the bottom line – profit and so there must be a gain for them somewhere! While we may not be sure where this gain is we, as patients, must be increasingly vigilant to ensure that we are receiving a truly informed choice of treatment based on evidence of benefit uninfluenced by any source of funding. If we are to maintain our confidence, or perhaps even regain our confidence, in the system, we have to be assured that any advice and treatment that doctors and healthcare professionals provide is totally uninfluenced, both consciously and subconsciously, by any private funding. There is no doubt that their intentions will be just this but…

NHS News

- **Patients to be protected - watchdog to oversee the work of all NHS healthcare professionals**

In the wake of the Bristol baby heart scandal, in August the Minister of Health announced that a new body is to be formed called the Council for the Regulation of Healthcare Professionals. The Council will replace what was described as the 'fragmented system whereby doctors and clinicians are responsible to their own professional bodies such as the General Medical Council and the Royal Pharmaceutical Society. The Dept of Health says that the new body will explicitly put patients first and will allow 'robust' public scrutiny. We will see…No doubt we will hear more!

- **Diabetes Specialist Nurses not included in nurse prescribing document**

The Dept of Health has sent out a consultation document on the government's proposals to extend nurse prescribing and that of pharmacists, chiropodists and optometrists. There is NO proposal as yet that diabetes specialist nurses should be allowed to prescribe insulin or any other diabetes medications. Consultation ends on October 9th 2001 and the proposals can be viewed on www.doh.gov.uk/nurseprescribing/

- **Doctors warn that the NHS Plan is not deliverable**

Dr Ian Bogle, Chairman of the British Medical Association, told their June Conference that his members were being made scapegoats for 'a system and a society with grossly unrealistic expectations.' He demanded an end to 'doctor baiting and doctor bashing'. Doctors warned that short consulting times are putting patients at risk and they recommended an increase from the present 7 minutes per consultation to 15 minutes. They also warned that the NHS plan is not deliverable without major increases in funding and in staff over and above the level the government has promised. The conference rejected plans to guarantee patients access to their GP within 48 hours. However, the Dept of Health's response was that the government's mandate is for investment to reform the NHS and to deliver more doctors, more support for them and more resources but there will be no veto over reform.

- **Cleanliness in Hospitals**

The government is to spend more money to clean up the dirty hospitals and provide a monitoring system for the future in England. Figures show that 5000 people per year die as a result of infections picked up in hospitals. Progress has already been made because the original list of 200 dirty hospitals has been reduced to 42. It is has not been said yet if Wales and Scotland are taking similar actions.

- **Countering Fraud within the NHS**

A new body has been set up to counter fraud and corruption within the NHS and it is called 'the NHS Directorate of Counter Fraud Services' [DCFS]. It expects everyone working within the NHS to work with it in its aims "to reduce fraud to a minimum within the shortest possible time and to free up resources for the best possible patient care." The DCFS has linked up with patient groups in order to try to achieve these aims. In 1999 an estimated £500m or more was wasted through mistakes or fraud, £15m was lost to people using stolen or forged prescriptions while GPs and pharmacists cost the NHS £16m in fraudulent claims.

- **NHS Plan Brings Yoga To Pensioners**

Pensioners will be able to practise yoga on the NHS as part of a plan to cut soaring rates of heart disease. Exercise courses, including weight training and aerobics, will also be available to people at risk from coronary heart disease, strokes or diabetes. This was announced by Alan Milburn as he took part in an exercise session with diabetes "sufferers".

- **Prescriptions by e-mail**

Two systems for electronic prescribing methods are being piloted in the UK - the push system is where the prescription is sent directly by e-mail to a pharmacy of the patient's choice and the relay system which enables the patient to go to any participating pharmacy. This is intended to allow GPs, nurses and pharmacists to work more closely together and the hope is that electronic prescribing will cut down on waste.

Is Type 1 Diabetes Being Side-Lined?

While understanding that Type 2 diabetes is increasing rapidly and therefore costing health services huge amounts of money, in IDDT's July 2001 Newsletter, we expressed fears that too little attention was being paid to Type 1 diabetes, especially the increasing incidence in young children. Interestingly there was an article about Type 2 diabetes in *'What Doctors Don't Tell You'* [Sept 2001] that looked at the treatment of Type 2 and the costs, querying the increasing use of oral medications and insulin and questioning whether there was evidence that this actually reduced complications. According to Dr Wolfe of Public Citizen, the leading US health consumer advocacy group, this increase is for three reasons – pharmaceutical companies, doctors and patients.

He says that with the increase in pills, experts have stopped stressing the role of diet, patients find a pill easier than following a diet and naturally pharmaceutical companies like people to take medication!

We will take another look at Type 2 diabetes in the next Newsletter.

Warnings!

Hypoglycaemia and breast feeding

A year after his wife's death, Andy Gregory-Smith has chosen to use his local newspaper, the Lowestoft Journal, to highlight the large changes in blood sugar levels that can take place during breast feeding. His wife died after driving her car erratically and eventually ploughing into a tree as a result of a hypo, presumably with no warnings. She had just been breast feeding her baby in a car park. Mrs Gregory-Smith had diabetes for 18years and was a member of MAD, Motherhood and Diabetes, a support group based in Ipswich. We thank her husband for trying to warn others of one of the possible effects of breast feeding for mums with diabetes. We hear much about the problems of pregnancy but little about what happens after the birth of the baby.

Diet Coke Again
If you drink Diet Coke make sure that you buy the English version! Diet Coke with foreign labelling has been reaching shops in the UK again. In a recent case in Reading the foreign label had been covered with a sticker in English but on careful examination of the contents list, sugar was at the top! This was discovered by a lady with diabetes when blood sugars shot up - apparently unaccountably. When she looked at the label she discovered she was not drinking what we know to be Diet Coke. Message – check the labels!

Should We Trust Them?

There is now a situation where the majority of research trials are funded by the pharmaceutical industry and this is not helped by governments' failure to independently fund research. In financial terms industry is well able to fund research, although as readers are aware, IDDT has questioned just how independent and unbiased this research really is. While we have no wish to offend the researchers

or academics, our health, well-being and even lives depend to a large extent on research. A great deal of secrecy surrounds drugs trials and this exists within the regulatory bodies in most countries as well as from the manufacturers themselves and so it is vital that we, the consumers, are not naïve in our understanding of the consequences of industry sponsored research.

While we must not become too cynical, we must recognise that industry is not spending billions on research for purely altruistic motives – understandably they want to sell their products, to increase their market share and their profit. They are in business and that is the nature of the game! But sometimes their methods are questionable and the lack of openness and access to information means that we, the consumers do not necessarily receive the true picture about a drug. We also have to remember that all too often only the trials that show a positive result in favour of the drug are actually published and those showing that it is either no better or that it is worse than existing treatments, may well not even be submitted for publication.

When we read published studies or newspaper headlines about some new 'wonder' drug, in making any judgements, we need to look at who funded the study, who has carried it out and who the authors of the final published paper were. If there are connections with the manufacturers of the drug under investigation we may choose to look at the research in a different light from that carried out completely independently of the manufacturers.

IDDT is not alone in worrying about these issues. In recent years many leading medical journals have insisted that if a study is funded by a drug company or the researchers and/or authors are employees of a drug company, then this has to be stated. Some journals go even further and insist that authors declare any conflict of interest - they have to state whether or not they have received any grants or financial assistance from drug companies. At least this way readers of the study know that there is drug company involvement and they can judge the reliability of the study in the light of this. It is important that people understand that not everything that is published is reliable, unbiased or necessarily honest. If you need proof, read on…..

"Drug company lies about Celebrex in the Journal of the American Medical Association" [JAMA]

Headline in the Washington Post August 5th 2001

Celebrex is a 'blockbuster' drug for treating arthritis and many of you may be taking it. It is a relatively new drug that has been widely prescribed to thousands of people replacing the older drugs. But the Washington Post reports:

The editors of JAMA received a drug company sponsored study involving over 8,000 patients who were tested with Celebrex for 6 months. The results showed that Celebrex was associated with fewer adverse reactions of stomach and intestinal ulcers and their complications, than the two older arthritis drugs, ibuprofen and diclofenac. The editors of JAMA were impressed and wanted to publish these results and asked medical expert, Dr M Wolfe to write an editorial to accompany the study and he wrote a cautiously favourable editorial.

However, later, as a member of the FDA's arthritis advisory committee, he was shown the complete information from the same study which showed a completely different picture. In fact the study had been a year long, not 6 months as he originally reviewed and the ulcer complications had all occurred during the second half of the study, although completed, not submitted to JAMA! So looking at the whole 12month study, the apparent safety advantages of Celebrex had all disappeared! The editor of JAMA is quoted "We are functioning on a level of trust that, perhaps, has been broken."

But who is involved in this level of trust?

Clearly the manufacturers were less than honest. But we must also look to the 16 authors of this study submitted with 6months missing data and question whether they can be trusted. There were 16

authors including 8 senior people from medical schools. Why aren't they up in arms about the study they carried out being submitted with missing data, especially when this gives a false impression of the drug's apparent advantages. The answer might lie in the fact that all the authors were either employees or paid consultants of the manufacturers of Celebrex! Their reputations must be tarnished and any future research looked upon with suspicion, but we can have little sympathy with them, as they force us into a position of wondering just who we can trust. No one has considered the 8,000 innocent participants in the study - they have been used and abused!

Meanwhile, the JAMA publication of the study with missing data and Dr Wolfe's editorial have probably helped to make Celebrex the blockbuster drug that it became.

Note - the manufacturer of Celebrex is Pharmacia and Pharmacia just happen to also own Monsanto, who have been the centre of many disputes over genetically produced crops and in some people's eyes have been less than caring on this issue!

Action being taken

As a result of the Celebrex story/scandal, the editors of 11 leading medical journals around the world told the New York Times [8.8.02] that they have agreed a new policy for reporting industry sponsored research. The full policy is to be announced in September [after the date of this article] but the policy will question papers listing academic scientists as lead authors when the studies were actually designed and the data analysed by drug company scientists. When the author's contribution to the research is questionable, the journals might not publish the paper with that author as lead investigator. This is an attempt to stop researchers being used as window dressers to give credibility to papers that are really the work of the drug companies.

Not diabetes, so why does the 'Celebrex story' matter to us?

- We are the consumers of healthcare and drugs are supposed to be for our benefit but we need to be assured that all research into drugs is honest and reliable so that we, and our doctors, are not presented with misleading information.
- We are the participants in research and giving time and effort to the study but we are also taking a risk – the drug under investigation may be beneficial or it may cause adverse reactions. We place our trust in researchers who are often our own physicians, and in return we should be able to trust that not only will the study be well-conducted but it will be honestly reported.
- increasingly people are seeking information about the drugs they take from sources other than their doctor. Therefore it is important that we are aware that even studies published in reputable journals can no longer be simply accepted without question.

Whatever our reasons for looking at published research, we need to be aware that it may not be quite what it seems and commercial hype and self-interest may be involved!

Blood Sugars And The Unexpected!

You may remember in our 'Grumbles' column some time ago, one man said that he was fed up with his consultant's parting shot on leaving of "Do try to get your blood sugars down"! Our man's comment was: does he actually think I'm not trying and why doesn't he tell me how to do it? From your comments to IDDT, this rang familiar bells with many people. It seems that the implied criticism that we are not really trying is not only an insult because the majority of us do try our best to maintain 'good' control, but it is an underestimation of the day to day difficulties of living with diabetes and maintaining 'good' blood sugars.

I was reminded of this on reading about research into the, MiniMed Continuous Glucose Monitoring System [Diabetologia, Feb 2001]. An Italian man with well-controlled Type 1 diabetes wore this continuous monitoring system the day before and the day of the semi-final football match between Italy and Holland on June 29th 2000. During the day

before the match his blood sugars were between 5 and 8.3 mmols/l. On the day of the match he followed his normal eating and injection regime and did not eat during the football match. But what happened to his blood sugars?

At the start of the match they started to rise and they peaked at 16.5mmols/l at the end of the match, the exact time that his team won by scoring a penalty. So the stress of watching his team sent this football supporter's blood sugars soaring! While we might wonder what would have happened to them if his team had lost, the message here is that controlling blood glucose levels is not just a matter 'trying harder'. Watching a football match is a normal everyday type event and there is no way that this man could have adjusted his insulin for this eventuality, he could only deal with the raised blood sugars at his next injection.

All too often we think of stress as being as a result of difficulties but this man's stress was caused by something that gave him pleasure! Just how many times day or a week do we experience similar unavoidable stressful events? However many it is, they will all help to increase the HbA1c results making the advice to *'try to reduce your blood sugars'* impossible to follow. Sometimes it is simply not possible to stop or prevent rises in blood sugars and this must be accepted as just one of the unsolved problems of Type1 diabetes. If this can be accepted, we will not feel to blame, or be blamed, when our HbA1c results do not achieve the targets set by the diabetes clinic.

Other Factors Involved In Diabetic Retinopathy

A new study in Belgium [ref 1] examined how often retinopathy occurs in people with different levels of blood sugars. Researchers analysed the information from more than the 1400 people with Type 1 diabetes that took part in the Diabetes Control and Complications Trial [DCCT]. None of the people had retinopathy at the beginning of the trial but the results showed:

- 10% of the people classed as having 'good diabetic control' developed retinopathy.
- more than 40% of the people with 'poor diabetes control' did NOT develop retinopathy.

The researchers concluded that other factors can also have an effect on the development of diabetic retinopathy.

These figures are very interesting, perhaps surprising and even reassuring. Most of us are not surprised that despite 'good' control, 10% of people still develop retinopathy because many of us know people that fit into this category. However, the fact that 40% of people with 'poor' control do not get retinopathy is surprising and perhaps higher than we have been led to believe. Again we all know people that don't appear to look after themselves or their diabetes very well, but seem to get away without complications, but 40% is really quite a high figure! This doesn't mean that we can all relax and not try to achieve the best control possible, but perhaps we can stop beating ourselves over the head with blame for past control levels if retinopathy does develop because clearly, there are more reasons than simply 'good' control.

There is often a tendency for research to look at people with good control, but perhaps research into this 40% with 'poor' control may provide some very useful information. Indeed, perhaps it would look at questions that many people with diabetes have been asking:

- Why have the statistics for visual impairment and blindness not significantly reduced during the last 15 years despite tight control, home blood testing and the introduction of diabetes nurses to improve care and education?
- Research has shown that a sudden drop in blood sugars after initial insulin treatment and after introducing tight control, may result in retinopathy. So are fluctuating or erratic blood glucose levels more likely to cause retinopathy than simply high blood

glucose levels that doctors would class as 'poor' control? Some people with 'poor' control [higher HbA1cs] may have higher blood sugars on average but these may be less erratic, so could this make this group less susceptible to retinopathy?

- The DCCT showed that the people with 'good control' also had more severe hypos, could hypoglycaemia be a factor in the development of retinopathy in the 10% that developed retinopathy, despite 'good' control.
- Was blood pressure an influencing factor in those that developed retinopathy?

Clearly this is an area well worth further investigation.

Ref 1 Diabetes Care, 2001;24:1275-1279

Resist And Learn - Advertising Drugs To The Public

In the July 2001 Newsletter an article by Bruce Beale expressed his concerns over the possible change in the regulations to allow pharmaceutical companies to advertise their products to the general public. He quoted the American experience where the pharmaceutical industry is top of all industries in the profit stakes and last year spent $1.7 billion dollars on TV adverts alone.

Now the European Commission has agreed to relax the rules on promoting drugs by allowing drug manufacturers to have 'disease awareness campaigns' that advertise their treatments. This is a close step towards direct to consumer advertising of drugs. The conditions first in line for this are AIDS, diabetes and asthma - so we are going to be the guinea pigs for this change!

Where is the harm?
Clearly advertising sells more drugs, otherwise the pharma industry would not spend $1.7 billion a year and nor would they be pressing for changes to allow them to advertise to consumers in Europe. Perhaps if we could be certain that the drugs they are selling are absolutely safe and went through a more rigorous approval process, then we might be tempted to see less harm. But the opposite is true. Again as a result of pressure from industry, the approval processes are faster and less rigorous than they used to be so that drugs are hitting the market sooner. The adverse effects, that can include death, are then picked up after the drug is on the market but if adverse effects occur then withdrawal from the market of such a drug can be a long process. Meanwhile during this time unsuspecting citizens continue to use it and are put at risk while the manufacturers are recouping their investment money! Troglitazone [Rezulin] for Type 2 diabetes was just such a drug. While it was withdrawn from the UK market after just 6 weeks, it was advertised and sold to millions of Americans for 2 years before being pulled from the market as the probable cause of nearly 400 deaths, 63 from liver failure.

Opposition to drug advertising
The Consumer Association - Figures from the UK Consumer Association [CA] show that the impact of advertising drugs in the US increased the drugs bill by 84% between 1993 and 1998 and that New Zealand had a similar experience when they allowed drug advertising. The CA predicts that the NHS drugs bill will rise hugely if drug advertising direct to the public appears in the UK.

They are campaigning to oppose all changes to the existing rules that prevent drug advertising arguing that the UK government must put patients' interests before the demands of industry. CA maintain that while there is little good quality information available to patients about prescription drugs, it is not appropriate for the pharmaceutical industry to provide this. They also conducted a survey that showed that only 6% of the respondents would trust drug companies to provide accurate information! Not surprising because industry can hardly be an unbiased provider of information when their aim is to sell more of their drugs than their competitors. So neither Bruce nor IDDT are alone in these concerns or their lack of trust in drug companies!

Of greatest concern should be that CA research shows that drug advertising is targeted at a narrow band of conditions and the most advertised drugs become the most popular, even when a generic or competitor's drug performs better. [Easy to see how this will apply to diabetes products!] It also showed that advertising information is generally of poor quality.

Health Action International Europe - This consumer organisation also criticises the EC move towards direct to consumer advertising of drugs and they have called upon the EU to provide evidence of a health benefit for this change. They also ask "Why does the European Commission believe that companies will act responsibly when their record is so poor overseas?" They provide three examples of this poor record including troglitazone for Type 2 diabetes. However, they do acknowledge that some consumer groups are in favour of drug company advertising but they also point out that these groups are 'well funded by commercial interests'.

The case for industry

Dr Trevor Jones from the Association of British Pharmaceutical Industry [ABPI] is quoted in the press as saying that the EC proposal is not about advertising but getting better information to patients. He maintains that "there is all sorts of junk on the internet and all sorts of misleading information but the pharmaceutical companies are prevented from giving quality information". Rather odd when the ABPI itself has a website accessible to the public giving the Patient Information Leaflets and the datasheets for all approved drugs.

The UK government position

This proposal came from the EU's G10 Committee, much of whose agenda is initiated by the UK and the prime mover in this is Lord Hunt, now the UK Minister responsible for medicine regulations and the promotion of the pharmaceutical industry. [Perhaps this is why he was so dismissive of our concerns over 'human' insulin adverse reactions!] The G10 appears to be a close replica of the UK Pharmaceutical Industry Competitive Task Force [PICTF] which was set up after a meeting between Tony Blair and the heads of AstraZeneca and GlaxoSmithKlein. Following this, Mr Blair made a personal commitment "to ensure that the future of the UK's pharmaceutical industry is even brighter". This PICTF is chaired by, yes, Lord Hunt under whom it has made a commitment to the international pharmaceutical industry to 'push at the boundaries of existing EU law that currently prevent direct to consumer advertising'. Is this all part of the present government's policy of increasing private sector involvement in the NHS? Interesting though that when the Conservative, Kenneth Clarke, was Secretary of State for Health his relationship with the pharma industry was far less cosy. He was so concerned about the closeness of the Dept of Health to the pharma industry that he tried, but failed, to get the official responsibility transferred to the Board of Trade.

So it seems that consumers will get little support from government against the move towards direct to consumer advertising. This is surely an issue that consumers, the medical profession and all health-related charities will oppose as it is difficult to see what benefits there can be for anyone, except industry. However, we know to our cost that the power and influence of the pharmaceutical industry usually wins, so the legislation controlling this advertising must be strict as consumer interests must be the priority in the crucial area of public health.

A reprimand is not sufficient!

There are numerous examples of drug companies being warned that their existing advertising is misleading and it seems that the only action taken against them is a reprimand but by the time the reprimand is made the advert will have already had the desired effect! For example, on May 1st 2001, Novo Nordisk were reprimanded in the US for violating federal regulations when they inaccurately represented their type 2 drug Prandin [repaglinide] in promotional materials. The FDA said Novo Nordisk understated the risks of Prandin and inflated its efficacy. They asked for the discontinuation of all such materials. This smack on the wrist is fine, but the damage is already done and could have already influenced prescribing in favour of Prandin!

Replacement Insulin For Lentard

Inappropriate information supplied to healthcare professionals and pharmacists by Novo Nordisk

When Novo Nordisk announced the discontinuation of Lentard MC in the UK by July 31st 2001, they widely circulated advice to healthcare professionals on the most suitable insulin to replace it. The same advice was issued on the website of Diabetes UK. As Lentard is a beef/pork intermediate-acting insulin, the IDDT Newsletter advised that Hypurin Bovine Isophane was the nearest replacement because there is no other beef/pork insulin on the market. However, the insulins that Novo Nordisk recommended are **NOT** the nearest animal insulin alternatives to Lentard MC in terms of their peaks of action and duration times.

Somewhat unbelievably they recommended that people on 2 daily injections of Lentard should change to Hypurin Porcine 30/70 Mix! Not only is this pork insulin when Lentard was largely beef but it is pre-mix insulin consisting of 30% short-acting insulin [soluble] and 70% intermediate acting insulin [isophane]. Therefore, a change to Hypurin 30/70 Porcine Mix could result in episodes of hypoglycaemia, especially if Lentard was used in combination with a short-acting soluble insulin.

IDDT wrote to both Novo Nordisk and to Diabetes UK on this matter. Diabetes UK later changed their recommendations. [Accessed 21.7.01]

Novo Nordisk's Medical Affairs Manager agreed that for people using soluble insulin with Lentard, a change to 30/70 mix without removing the soluble insulin ***"could have serious consequences". But he added that he was sure that this would not happen because "Lentard is an old-fashioned insulin and it is inconceivable that anyone would be combining this insulin [Lentard] with a soluble insulin before meals."***

We asked why it was so inconceivable, pointing out that the action profile for Lentard is very similar to those of beef and pork Hypurin isophanes and to Human Monotard. Therefore it is quite conceivable that people would use Lentard with a short-acting soluble insulin. Indeed, one of the people that raised this issue with IDDT was on exactly this 'inconceivable' regime! That Novo class Lentard as old-fashioned is quite irrelevant - Lentard has been around for a long time but it has not been replaced with insulin proven to be superior. We would like our treatment to be based on evidence of benefit not fashion!

The correct information is as follows:

- Lentard is a zinc suspension insulin and as such the most appropriate alternatives are Hypurin Bovine Isophane or Hypurin Porcine Isophane, both manufactured by CP Pharmaceuticals Ltd. As Lentard is 70% bovine insulin, the Hypurin Bovine Isophane is the nearest alternative to Lentard.
- People that need a slightly longer acting insulin may find Hypurin Bovine Lente a better alternative.

Novo Nordisk has promised to issue advice on the most appropriate replacement insulins when they discontinue all their pork insulins, "even if these are made by other manufacturers". But the Lentard experience is a salutary lesson – for whatever reason, inappropriate recommendations were made that could have led to unnecessary hypos. Lentard was only taken by small numbers of people, but thousands of people will be affected when Novo Nordisk withdraws pork insulin and they will need reliable, correct information and now it seems, preferably from an independent source.

Novo Nordisk has NOT announced the date for withdrawal of their pork insulin in the UK, but IDDT will be regularly publishing details of the pork insulins that are available as alternatives.

- **Users of Novo Nordisk pork insulins will NOT have to change to genetically produced 'human' insulin. Pork insulins are**

produced by CP Pharmaceuticals in vials and cartridges for pens. The nearest equivalent replacement insulins are as follows:

Novo Nordisk porcine insulins	Nearest replacement insulin by CP
Pork Actrapid [soluble]	Hypurin Porcine Neutral [soluble]
Pork Insulatard [isophane]	Hypurin Porcine Isophane
Pork Mixtard 30 [pre-mix]	Hypurin Porcine 30/70 Mix [pre-mix]

The Cochrane Metabolic And Endocrine Disorders Group - Consumers Summaries

In the July 2001 Newsletter we reported on the UK Cochrane Collaboration meeting earlier this year. The article pointed out the advantages of looking at Cochrane systematic reviews of research topics to provide evidence of the benefits or otherwise of various healthcare treatments to help us, the consumers, and our doctors in health related decision making. We promised to give you details of some of the summaries that are of particular interest to us as people living with diabetes. We hope that you will find them useful and interesting:

"Protein restriction for diabetic renal disease"
Diabetic renal disease (nephropathy) is a leading cause of end-stage renal failure. The objectives of this review were to determine whether protein restriction slows or prevents progression of diabetic nephropathy towards renal failure.

Reviewers' conclusions: The results show that reducing protein intake appears to slow progression to renal failure, but some questions remain unanswered. The first is what level of protein restriction should be used? The trials aimed for a daily intake of between 0.3 to 0.8 g/kg of protein. The second concerns compliance in routine care - what level would be acceptable to patients? The third concerns long term outcomes - the present trials use proxy indicators such as creatinine clearance rather than outcomes such as time to dialysis or prevention of end stage renal failure. All trials were carried out in patients with insulin-dependent diabetes. It remains to be seen if a lower protein intake would slow the progression of nephropathy affecting the non-insulin dependent diabetic population.

"Very tight versus tight control for diabetes in pregnancy"
Pregnancies complicated by pre-existing insulin dependent diabetes are high risk for a number of poor pregnancy and neonatal outcomes. The objective of this review was to assess the effects of very tight glycaemic control in established insulin dependence.

Main results: Two trials involving 182 women were involved. The two trials were difficult to compare. Maternal hypoglycaemia was more common among women whose diabetic control was very tight compared to tight control based on one trial. There was no difference detected in perinatal outcome between the groups.

Reviewers' conclusions: There appears to be no clear evidence of benefit from very tight glycaemic control for pregnant diabetic women. Since very strict control may have a substantial impact on lifestyle, this suggests caution in advising such a degree of control.

"Systems for routine surveillance for people with diabetes mellitus"
There is wide variation in the extent of general practice involvement in diabetes care. The objectives of this review were to assess the effects of involving primary care professionals [GP based] in the routine review and surveillance for complications of people with established diabetes compared with secondary care specialist [hospital based] follow up.

Main results: Five trials involving 1058 people were included. Results were heterogeneous between trials. In those schemes featuring more intensive support through a prompting system for general practitioners and patients, there was no difference in mortality between hospital

and general practice care. HbA1 tended to be lower and losses to follow up were significantly lower in primary care. However, schemes with less well-developed support for family doctors were associated with adverse outcomes for patients. Quality of life, cardiovascular risk factors, functional status and the development of complications were infrequently assessed.

Reviewers' conclusions: Unstructured care in the community is associated with poorer follow up, greater mortality and worse glycaemic control than hospital care. Computerised central recall, with prompting for patients and their family doctors, can achieve standards of care as good or better than hospital outpatient care, at least in the short term. The evidence supports provision of regular prompted recall and review of people with diabetes by willing general practitioners and demonstrates that this can be achieved, if suitable organisation is in place.

"Interventions to improve the management of diabetes mellitus in primary care, outpatient and community settings "
Diabetes is a common chronic disease that is increasingly managed in primary care. Different systems have been proposed to manage diabetes care. The objectives of this review were to assess the effects of different interventions, targeted at health professionals or the structure in which they deliver care, on the management of patients with diabetes in primary care, outpatient and community settings.

Main results: Forty-one studies were included involving more than 200 practices and 48,000 patients. The studies were heterogeneous in terms of interventions, participants, settings and outcomes. The methodological quality of the studies was often poor. In all studies the intervention strategy was multifaceted targeting health professionals and/or the organisation of care eg arrangements for follow-up. In 15 studies patient education was added to the professional and organisational interventions. A combination of professional interventions improved process outcomes. The effect on patient outcomes remained less clear as these were rarely assessed. Arrangements for follow-up also showed a favourable effect on process outcomes. Multiple interventions in which patient education was added or in which the role of the nurse was enhanced also reported favourable effects on patients' health outcomes.

Reviewers' conclusions: Multifaceted professional interventions can enhance the performance of health professionals in managing patients with diabetes. Central computerised tracking systems or nurses who regularly contact the patient can also improve diabetes management. The addition of patient-oriented interventions can lead to improved patient health outcomes. Nurses can play an important role in patient-oriented interventions, through patient education or facilitating adherence to treatment.

"Angiotensin converting enzyme inhibitors in normotensive diabetic patients with microalbuminuria"
The objectives of this review were to examine whether the progression of early diabetic renal disease to end-stage renal failure may be slowed by the use of angiotensin converting enzyme inhibitors [ACE inhibitors] for reasons other than their antihypertensive properties, so that they have value in the treatment of people with diabetes with microalbuminuria [protein in the urine] and normal blood pressure[normotensive].

Main results: Albumin excretion rate fell for patients on ACE inhibitors in 12 of the 13 studies but did so for only two of the 13 groups on placebo [dummy pill]. Treatment provided a significant reduction in albumin excretion rate in both insulin and non-insulin dependent diabetes. Treatment with either captopril, enalapril or lisinopril reduced albumin excretion rate in comparison with control patients.

A significantly greater lowering of blood pressure was experienced by people with normal blood pressure at the outset in the ACE inhibitor than in the placebo group. Average HbA1cs fell a little in the treated patients and rose in the controls, the difference being just significant. The difference in changes in glomerular filtration rate did not reach statistical significance.

Reviewers' conclusions: The use of ACE inhibitors can arrest or reduce the albumin excretion rate in microalbuminuric normotensive diabetics, as well as reduce or prevent an increase in blood pressure. But, given the drop in blood pressure in patients on ACE inhibitors, it is not certain that the reduction of albumin excretion rate is due to a separate renal effect. A direct link with postponement of end-stage renal failure has not been demonstrated. There appear to be no substantial side effects.

Consumer summaries of reviews from other Cochrane Groups

Cranberry juice and urinary infections
This review examined the evidence to look at whether cranberry juice can prevent urinary tract infections in people that are prone to them – some women with diabetes fit into this category. The reviewers found that many of the research trials were of poor quality and that there is not enough evidence for or against cranberry juice as a prevention for these infections. So if cranberry juice works for you, this seems to be the only evidence there is!

Vaginal Infections
There is no difference between using oral or vaginal anti-fungal treatments for vaginal infections caused by candidias [thrush] but oral treatments are more expensive.

Diet, cholesterol and obesity
Dietary advice by dietitians to lower cholesterol was more effective than advice by doctors [in the short term] but was possibly not more effective than using self-help resources. There was no evidence to suggest that dietary advice given by dietitians was more effective than that given by nurses.

Depression
People who receive primary care counselling for psychological problems are more likely to feel better immediately after treatment and be more satisfied than those who receive normal GP care. It is not clear whether counselling is superior to GP care in the long term.

Stored Insulin - Fascinating Information

IDDT has tried to make people aware of the desperate need for insulin and other diabetes supplies for people in poor countries. In these countries it is important to know how long insulin can be stored and still maintain it's potency. But the discontinuation of animal insulins is no longer an issue just for people in poor countries, for instance, there is a total lack of beef insulin in the US. Some people in the US have bought several years worth of beef insulin - one lady I know has even bought a second fridge solely for this purpose. She can't use 'human' or pork insulin, importing beef insulin from the UK is an option but it is not without problems, so what choice has she?

I hear you say, but what about the expiry date and how long will her stored insulin remain potent and effective at lowering her blood glucose?

Expiry dates
According to the International Diabetes Institute, which incorporates the World Health Organisation Centre for Diabetes and Health Promotion, insulin manufacturers are required to place an 'expiry date' on each container of insulin but this date appears to be a nominal one and not based on available scientific evidence. The expiry date is usually 2 years after manufacture but varies between manufacturers and between countries. [ref1] The date is determined partly by commercial considerations and also allows for a margin of error when storage conditions by the dispenser and consumer are unknown.

Note - like food labelling, the expiry date does mean that you, the patient, would have no legal redress if you used 'out of date' insulin and anything went wrong so IDDT recommends that you follow the manufacturer's instructions.

Is insulin safe if it is stored for years?

Insulin potency
By potency we mean the effectiveness of insulin to lower blood glucose

and we know that this decreases with exposure to light, temperature and vibration. This is why correct storage of your insulin is important because in use insulin has been exposed to all these factors and its potency may reduce so affecting blood glucose levels – they are likely to be higher.

The following facts are known [ref1]

1. The potency of insulin decreases very gradually over time and the degree of reduction depends on the storage conditions.
2. Insulin should be stored in the dark as exposure to sunlight decreases its biological activity. The optimum storage is in the dark at temperatures between 2 and 8° C. and freezing should be avoided.
3. If there is a loss of potency as a result of storage at high temperatures for long periods, then the breakdown products of insulin are not harmful in any way - unlike expired antibiotics, for example. So the insulin is safe to use but it may not be fully effective.

This table shows the extremely long periods of time required before the potency is reduced by even small amounts – quite a surprise to most of us!

Time of storage of insulin preparations at various temperatures until biological potency is reduced by 2% and 5% respectively

Insulin preparation	4° C	15° C	25° C	40° C
Actrapid	36/92 years	5/13 years	12/31 months	5/14 weeks
Semilente	45/115 years	4/11 years	7/18 months	2/5 weeks
Lente	36/91 years	3/9 years	5/14 months	1/ 4 weeks
Rapitard	22/55 years	3/8 years	7/17 months	3/7 weeks
Ultralente	19/48 years	2/5 years	4/10 months	1/3 weeks

Information source: 'Galenics of Insulin' by J Brange M.Sc et al: [Novo Research Institute, Denmark] Springer-Verlag, 1987

In emergency situations – poverty, floods, earthquakes
Provided insulin is stored appropriately, it may be used for several years and certainly for at least 12 months after the nominated expiry date. This is particularly important when insulin is provided in an emergency situation, as it can be lifesaving. It is a different sort of emergency for my friend in the US and other people who are building up their stocks of animal insulin because they cannot use the only insulin available to them, 'human' insulin, but it is for them an emergency. In emergency, it is unimportant whether the potency is 95% or 99% and in the unlikely event of the potency dropping to 90%, adjustment of the insulin dose would overcome the problem.

Ref 1 Information on storage of insulin. Dr M Cohen, July 1996

What's In The Pipeline?

Innovo – the first insulin doser.

This is the latest insulin delivery device developed by Novo Nordisk. It is not like the pen but similar to a pager in size and shape to make it easier to hold for small hands. Some of its features are as follows:

- Built-in memory that records the time elapsed since the last injection and the dose injected.
- Large digital display
- Injection countdown timer to show when the required amount of insulin has been delivered
- Needle support pillar to stabilise the device during an injection
- Dose dialing mechanism that can be adjusted up or down to prevent wastage and to make it impossible to dial up more insulin than remains in the cartridge, so stopping the worry about under-dosing.

Innovo is designed to use 3.0ml cartridges of most Novo Nordisk

'human' insulins. It is free of charge at hospital diabetes clinics and replacements are available from pharmacies on NHS prescriptions [NHS reimbursement price £25.00]

Insulin determir - new intermediate-acting insulin being developed
Insulin determir is an intermediate-acting insulin analogue developed by Novo Nordisk now undergoing trials but unlike Lantus it is an intermediate-acting insulin. According to Novo, it is absorbed with less variability and provides a flatter action profile than the present intermediate insulins. Comparitive trials showed that the absorption of existing intermediate-acting insulins varied by 20-30% on a daily basis. [No wonder we have problems with varying blood sugars!] When given overnight, determir had a later onset of action resulting in less night hypos. However, a report published in Diabetes Care [Feb 2001] showed that people had to take 2.35 times more determir than normal intermediate-acting insulin.

Automatic insulin pump
Doctors in France and the US are pioneering an implant which automatically releases insulin into the blood stream from a mini-pump just under the skin. The pump is 2 inches in diameter and is placed in the abdomen. The insulin is stored in a highly concentrated form in a 15ml reservoir that has to be topped up every 3 months by a small injection through the skin. In effect this is a small artificial pancreas with a sensor that would release minute amounts of insulin throughout the day when needed.

Insulin pill may be ready in 10 years
Insulin cannot be taken orally because it is a hormone that is broken down by the acids in the stomach but scientists at Purdue University, Indianopolis, believe they have found a way to produce insulin in pills. The 'breakthrough' is a new acrylic-based, gel-like coating on the pill that would allow the pills to survive the digestive processes of the gut and the insulin to gradually seep into the bloodstream through the small intestine. In tests on animals up to 16% of the insulin in the coated pills reached the bloodstream compared with 50-80% with insulin injections. The scientists believe that the pill could reach the market in 10 years providing that the idea attracts industry funding.

Update on Inhaled insulin
Exubera is the Pfizer/Aventis development of inhaled insulin. Pfizer have revealed that four times as many people on Exubera developed antibodies against their inhaled insulin compared to those taking insulin injections. As we know antibodies are natural proteins created by the body to destroy what it considers to be 'foreign invaders'. The study comparing inhaled insulin with injected insulin in 299 people with Type 2 diabetes showed that Exubera was as effective at lowering blood sugars as injected insulin and the side effects were similar but 20.4% of those taking Exubera developed antibodies compared with 5.1% of those using injected insulin.

The manufacturers say that there appeared to be no harm caused to the patients by the antibodies but the concern expressed by others is that the effects of Exubera might wane after long term use because the antibodies may overwhelm the insulin and make it ineffective. In July Pfizer said that they are likely to delay seeking approval for Exubera because the FDA require more clinical data. The announcement by Pfizer in June caused shares values in the company making the inhalation device to tumble!

IDDT's "Look In Your Fridge campaign"

Is there any unopened, in-date insulin there?
This was our message in the poster with the July Newsletter and your response was tremendous! We would like to thank all of you for sending your in-date, unopened and unwanted insulin to IDDT. We are especially grateful to the healthcare professionals who have taken the time and trouble to pack up and send us the unwanted insulin that patients return to them. IDDT has sent it to 'Insulin for Life', the organisation that collects insulin and test strips to send to people in real need as part of a humanitarian emergency programme.

We don't need to remind you that the problem in poor countries is no longer a simple matter of shortage of insulin supplies but shortage of affordable insulin. The cost of insulin for one person can be 50% of a family's income and this is one of the main reasons why people with diabetes are NOT receiving the insulin they need to stay alive. In this situation it is not diabetes that is killing people - the real killer is the high price of insulin.

While we wait for drug companies to show compassion for people in poor countries, IDDT will continue its campaign to collect any unwanted insulin or blood glucose testing strips knowing that we are saving or prolonging lives.

So maybe you have changed your insulin and have unwanted, unopened and in-date insulin in your fridge. Please put it in a jiffy bag and send to IDDT, PO Box 294, Northampton NN1 4XS.

From Our Own Correspondents

GlucoWatch - first hand experience
Dear Jenny,

I was pleased to see the article about the GlucoWatch Biographer in the July 2001 Newsletter giving some of its drawbacks. I would hate people to buy it expecting it to be wonderful, especially as the 'watch' and the sensors cost so much!

I was one of 4 people involved in trials for the GlucoWatch at Guy's Hospital and I think that it is very important that people are not misled by the adverts for this device, especially as it is so expensive both to buy and to run. We were all given the GlucoWatch and could have kept it at the end of the trial but it says a lot that three out of the four of us gave it back!

Most of the drawbacks were practical ones or just a nuisance. It has to be calibrated every time you use. When you decide to use the 'watch' it has to be worn for the full15 hours without taking it off so that the cycle is not interrupted. It also is not waterproof or damp proof which means that you can't have a bath or shower during that 15 hours and even washing up was a problem for me as I splash water about quite a lot!

You have to be careful not to knock it or the seal between the sensor and your arm is broken and it skips results. One of the people trying it was a builder and therefore at risk of knocking. You can't wear it on any part of the body that is hairy so he tried shaving his leg and wearing it there but it wouldn't stay on. Another person with an energetic job, tried wearing it on her upper arm so that it did not get caught up, but she sweated too much so it didn't work! I didn't have a problem with it during the night but some of the others did because it kept bleeping, even when they didn't have high or low blood sugars – presumably they kept knocking it.

Finally I got quite a burn mark on my wrist when wearing it. So all in all, in it's present form it was not of any help. I think that the idea is excellent and I hope that one day it will be perfected but in my experience, it is certainly not yet the breakthrough that we all want so much.

Ms A.M.
South East

Latest information - IDDT was concerned that the GlucoWatch and the sensors required for it was being marketed the UK before the US, where they are manufactured. Indeed, it was put on the market here before the FDA had actually approved the manufacturing facilities for the sensors which was not obtained until August 2001.

IDDT contacted Cygnus, the manufacturers and the Medical Devices Agency [MDA]. The MDA informed us that the Glucowatch is a Class IIa [medium risk] device but when advertised it had not been

evaluated by them and they thanked IDDT for informing them that the GlucoWatch was being marketed in the UK. Cygnus then informed IDDT and the MDA that the GlucoWatch is CE marked which means that the manufacturers are declaring that the device meets all the requirements under the legislation for safety and therefore can be sold anywhere in Europe.

A further letter from the MDA informed us that the matter has been passed to the Compliance and Adverse Incident Dept of the MDA for further investigation but no third parties [meaning IDDT] are allowed to know the findings of this type of investigation. [Presumably because the UK has no real Freedom of Information Act!]

Like Ms A M, IDDT sees continuous monitoring with an alarm system as the answer to many of the day to day difficulties of living with diabetes but we have to wonder if the GlucoWatch is on the market too soon. It needs to be better and more reliable than in its present form. It is also very important that the adverts and articles about it are not misleading. The cost, now that the introductory offer is over, is £350 for the device and £50 per box for 16 sensors, so the price of the sensors make the running costs almost unaffordable for most people.

Side-lining of Type 1 – with an amusing anecdote!
Dear Jenny,

We were interested in the article about Type 1 diabetes being side-lined in favour of Type 2. I thought you might be interested in the misconceptions my husband has faced since 1979 when he was diagnosed with Type 1. We find that attitudes do seem to have changed with the prominent coverage of Type 2.

When we first met my friends had only vaguely heard about diabetes and indeed my mother's reaction was 'you'd better find out what I can feed him'. Now everyone thinks they are expert because they have read about Type 2 in newspapers and magazines.

My husband has been asked if he used to be overweight and is that why he has diabetes, implying that he's to blame! He has never been more than 10 stones, works long shifts and runs 20 miles a week. When we were on an all-inclusive holiday two years ago, a lady asked where my husband had gone. I explained that he had gone to do his injection before his meal. She said that she had diabetes and took 1/2 a tablet a day and had to watch what she ate. I explained that my husband had 4 or 5 daily injections according to his shift pattern. Her reply was, "Oh he's got the less serious type" and this was her explanation. She had joined the Diabetes Association and received their magazine that she said "was full of people with her type of diabetes and how they coped and hardly ever mentioned people that got diabetes at a young age". So she assumed that diabetes needing insulin injections was less serious and people find it easier to live with! So she equated coverage with problems and the more coverage given to Type 2 the more people will think like her and dismiss people with Type 1.

Mrs TD
North

Dear Jenny,

Many thanks for the July Newsletter – as usual great value in every word. The side-lining of Type 1 diabetes makes me hopping mad. I have had Type 1 diabetes for 41 years and thanks to IDDT's information, I am much better in all ways back on animal insulin. I had absolutely no help in my change back to animal insulin from my Consultant who basically thought I was mad! My GP was much more helpful and said let's give it a go.

I have battled for some 40 years to make my life as normal as possible but all too often this results in my diabetes being ignored by other people, even members of my own family! At the end of the day, it is not a 'normal' life but with a little more tolerance and understanding it could be a great deal better. I don't have some dreadful disease but what I do have won't actually disappear if you don't look!

When will the public, both professional and otherwise, understand diabetes and the differences between Type 1 and Type 2 diabetes? The continual emphasis on Type 2 diabetes in the press is certainly not helping people with Type 1 diabetes. Please can we somehow educate everyone to be a little less blinkered so that the importance of Type 1 diabetes is not lost in the hype about Type2.

Ms G.J.
London

Insulin Pens Dribble From The Tip Of The Needle

The new 3.0ml pens dribble more than1.5ml pens

With the introduction of the larger 3.0ml pens and the withdrawal of some of the smaller 1.5ml pens, a study [ref1] that compared 6 pens of both sizes provides useful information to ensure that you receive the intended dose of insulin. The pens used were Lilly Saline Pen 3.0ml, B-D pen 3.0ml, NovoLet 1.5 and 3.0ml, NovoPen 1.5 and 3.0ml.

In the study 20 people injected sterile saline with the needle being withdrawn after 1, 3, 5 or 7 seconds. Any dribble was collected on filter paper and weighed.

Results showed:

- There was minimum of dribbling from the 1.5ml pens.
- 8 out of 20 NovoPen 3.0ml and B-D 3.0ml pens, 16 out of 20 NovoLet 3.0ml and 19 out of 20 Lilly 3.0ml pens dribbled even after the longer 7second hold-in time.
- The different brands of 3.0ml pens dribbled different amounts with the B-D 3.0ml leaking the least followed by the NovoPen 3.0ml, the Novolet 3.0ml and the Lilly Saline Pen 3.0ml leaking the most, at nearly twice that of the Novolet.

As a result of the great number of leakages from 3.0ml pens even after 7 seconds, the researchers recommend a hold-in time of at least 10 seconds. They also point out that with 1.5ml pens where the leakage is minimal, the risk of dribbling was not a major issue. Then the hold-in time was only considered because of the risk of the insulin leaking from the skin or blood being drawn back into the cartridge.

But interestingly none of the pen manufacturers recommend such a long hold-time for their 3.0ml pens – Novo Nordisk recommend 6 secs for both NovoPen and NovoLet, Lilly recommend 5 secs and BD do not mention hold-time.

Pens have to be reliable
If you receive different amounts of insulin each time depending on hold-in time, then this may lead to varying blood sugar levels and poorer control. It seems that the 3.0ml pens have the disadvantage of insulin loss due to dribbling that is not a problem with 1.5ml pens. We have to wonder why all the manufacturers are withdrawing their 1.5ml pens which this study demonstrates to be more reliable for injecting the intended dose.

Other factors that affect intended dose
Air bubbles. BD recommends the discharge into the air of 4units of insulin and thereafter 2units until a drop of insulin is seen at the tip of the needle. Lilly recommends discharging 2units before every injection. The information for the NovoPen 3.0ml is that 2units are discharged before every injection.

Needle replacement - loss of insulin and air bubbles. All 3 of these manufacturers recommend that the needle is removed after every injection but for different reasons!

- Novo Nordisk's reason is 'to avoid liquid leak' [NovoLet]
- Lilly's is 'to avoid air entering the vial' [in pre-filled pen1999], to avoid needle blockage and to keep sterility [in Humalog

pen package]
- BD's reason is ''maximum safety and comfort'.

So remember when using pens, especially 3.0ml pens, that the dose injected can be affected by hold-in time, dribbling and air bubbles could result in different amounts of insulin being injected and variable blood glucose results and poorer blood sugar control.

Ref 1 Practical Diabetes, June 2000, Vol 17, No 4

The New York Disaster

IDDT must express our deepest sympathies to all the families of all the people who lost their lives as a result of the terrorist attack on the World Trade Centre and to the people of America.

We now all realise that none of our lives will ever be the same again for many different reasons. The increase in security on flights is something that will directly affect people with diabetes because sharp objects are not allowed in hand luggage. Syringes, injection pens and lancets for blood testing are all sharp objects. At the time of writing the information that IDDT has received is that a doctor's letter will be required to state that you require have insulin dependent diabetes and will need to carry injection and testing equipment with you on the flight.

Many people already do this to avoid any confusion or misunderstanding about syringes being carried for drug abuse purposes and so this will be nothing new. But it is now an understandable requirement for security reasons and one which I am sure we all understand and that will not be seen as discrimination against people with diabetes. We will keep you informed of any further developments.

New Insulin On The Market

Lantus 24hour insulin analogue now available

Lantus, made by Aventis, is the first insulin analogue to provide 24hour long-acting basal cover with one injection per day. It is a 'synthetic', analogue insulin that provides a relatively constant level of activity for 24hours without a real peak of activity. The intermediate-acting insulins [isophanes] only last for up to about 14 hours and peak several hours after injection – thought to be a cause of night hypos.

With great excitement diabetes experts are claiming that ***'Lantus is an exciting new treatment option. Lantus may change the way diabetes is treated because it may allow people with diabetes who have needed twice daily injections of long-acting insulin to only take one injection a day to manage their basal insulin needs.'***

But let us not forget that before the major drug companies reduced the range of animal insulins, 24hour beef insulins with little or no peak of activity were frequently used! This is not a new treatment option at all, just a re-discovery of the advantages that some of the so-called 'old-fashioned insulins' have always had. Hypurin Bovine Lente and Hypurin Bovine PZI made by CP Pharmaceuticals, have never stopped being available and they offer 24hour basal cover, just like Lantus!

Equally interesting, is the statement by Aventis that ***'in order to provide 24hour full basal cover with the intermediate-acting insulins that most people are now using, it is necessary to have 2 injections per day – morning and evening.'*** So why are so many people aiming for tight control using the regime with one injection of intermediate-acting insulin before bed and short-acting before meals? While IDDT hates to say "I told you so", several times the Newsletter has explained that this regime means that the longer-acting insulin runs out half way through the next day. This in turn means that for about 10 hours of the day, there is no longer-acting insulin running in

the background and blood glucose control is relying entirely on the short-acting insulin. This is likely to result in more erratic blood sugars, even an increase in dose to compensate for high blood sugars that in turn can lead to more hypos. It is interesting that Aventis are now agreeing with us, so perhaps Lantus will draw professionals' attention to the need to consider the reliability of a regime of one injection of intermediate-acting insulin before bed. Those of us that have been around a long time remember that good basal 24hour insulin cover was always classed as vital to good control and most people used 2 daily injections of intermediate-acting insulin to provide this. We also remember that this regime changed with the appearance on the scene of the shorter and faster acting 'human' insulin and pens. So we must welcome the re-discovery of this regime by Aventis!

More about Lantus

- The adverse reactions are listed as similar to those of other insulins - hypoglycemia, lipodystrophy, skin reactions and allergic reactions.
- It is for the treatment of Type 1 diabetes in adults and children over 6 years old and Type 2 diabetes where long-acting insulin is required.
- The safety and effectiveness of Lantus injection given once-daily at bedtime was studied in over 4,000 patients in six open-label, randomised, parallel studies and was compared to that of intermediate-acting 'human' insulin. The results showed that there was a 25% reduction in night hypos in the Lantus treated groups and also a reduction in weight increase in this group. However, the Lancet [Vol 356, Aug 5 2000] reported that hypoglycaemia was defined as less than 2.0mmols/l. In other words, hypos between 4 and 2 were not counted! The Lancet also reported that no change in overall glycaemic control had yet been shown with Lantus when compared to intermediate-acting insulin.
- Lantus has the advantage of being a clear liquid not milky and therefore does not have to be rolled to re-suspend as with other 'milky' longer-acting insulins.
- Safety warning – Lantus must not be diluted or mixed with any other insulin because the onset of action time may be altered in an unpredictable manner.

Quitting Smoking - Zyban

There cannot be a person in the land that does not know that smoking is bad for your health and equally most people with diabetes know that smoking and diabetes is even worse. The evidence that smoking increases the risks of the major complications of diabetes is clear and smokers with diabetes have a greater risk of:

- Heart attack, thrombosis, stroke and atherosclerosis [narrowing of the blood vessels]
- Neuropathy and nephropathy [nerve and kidney damage]
- Raised blood pressure
- Raised blood glucose levels
- Raised protein in the urine – a sign of possible renal damage.

All of this was quite rightly pointed out in Balance Sept 2001 by Diabetes UK along with advice on how to stop smoking. While IDDT tries not to be critical of other journals, we were concerned to see that one of the recommended methods to help people to stop smoking was the use of Zyban, albeit that Balance recommended that it was used after consultation with your GP. [Unavoidable anyway because Zyban is a prescription only drug!] Their accompanying Heart Supplement contained a little more information but the

reason for our concern is that the article did not warn that earlier this year updated guidelines were issued for Zyban's after an air stewardess died as a result of adverse reactions after taking Zyban. The manufacturers, GlaxoSmithKline, then admitted that 35 people had died after taking the drug. New guidelines were issued by the Committee on Safety of Medicines after they received 5,000 'yellow cards' used by GPs for reporting adverse reactions!

But of greater concern to us is that the article in Balance omits to say that there are Special Warnings for Zyban that apply to people with diabetes:

- **Zyban should not be prescribed or only prescribed if absolutely necessary and used under extreme caution using the lower daily dosage to people in certain categories, one of which is people with diabetes being treated with insulin or tablets.**
- **The other known side-effect of Zyban is that it can cause seizures and therefore should not be prescribed for people who have a history of seizures and some people with diabetes are prone to seizures when they have severe hypos.**
- **There are contra-indications for the use of Zyban with other drugs, one of which is beta blockers, again a drug that people with diabetes may well be using.**

Clearly people with diabetes should try to stop smoking but it would seem that other methods may well be preferable to the use of Zyban.

Note: help for smokers is available from the NHS Smoking Helpline on 0800 1690 169 or their websitewww.givingupsmoking.co.uk

More Thanks

To the Royal Marines Band and Barbara Holmes

Our grateful thanks go to Barbara Holmes and her family for organising the concert of the Royal Marines Band on the Isle of Wight in July. The concert raised the fantastic amount of over £3500 for IDDT and by all accounts was enjoyed by everyone.

To you for buying your IDDT Christmas cards

Thank you to everyone who has already purchased their Christmas cards, we very much appreciate your help and support. If you haven't already ordered them, please think about doing so, Christmas is not that far away!

If you have lost your order form, then contact IDDT tel 01604 622837, fax 01604 622838 or e-mail cards@iddtinternational.org

New From IDDT

Looking after Your Insulin - IDDT has updated the leaflet "Looking After Your Insulin" the main thrust of which is to point out that you should always discard 'in use' insulin after 28 days. [In use means any insulin vials or cartridges that have been punctured.] The new leaflet covers the information about storage of some of the newer insulins and general information about holidays and travelling.

Kidneys - in addition to the new IDDT leaflets as advertised in the July 2001 newsletter, there is now information on the website about diabetes and the kidneys and this has been produced in leaflet form for those without access to the internet.

If you would like copies of the new leaflets, please contact IDDT, PO Box 294, Northampton NN1 4XS, tel 01604 622837 or e-mail leaflet@iddtinternational.org

Can You Help?

A group of our members are taking part in a 'long distance learning course' in diabetes management. One of their tasks is to design an information leaflet on any aspect of diabetes to be displayed in

public areas such as schools, hospitals or the workplace. They would welcome your views on how you feel that insulin dependent diabetes should be portrayed in a poster. Please help by just dropping a note to Jenny Hirst, IDDT, PO Box 294, Northampton NN1 4XS or email jenny@iddtinternational.org

Around The World

Pork Insulin From Lilly Still avaliable
Eli Lilly do not supply pork insulin in the UK but they are the only supplier in countries such as the US and Canada. All beef insulins in these countries have already been withdrawn leaving pork insulin as the only available animal insulin for people who have adverse reactions to 'human' insulin. Unfortunately some people find that pork insulin has similar effects as 'human' insulin, but for others pork insulin is a better option than 'human' and certainly worth a try before going to the lengths and expense of importing beef insulin from the UK. Naturally people are concerned about the future supplies of pork insulin, so IDDT wrote to Lilly to inquire about future availability.

On August 15th 2001 we received a letter from John H Holcombe, MD, the Medical Adviser in Lilly's Diabetes Care Division. While saying ***"the advantages of human insulin products and insulin analogs have been clearly demonstrated in carefully conducted clinical trials of diabetes patients around the world".***

He goes on to say: ***"I am pleased to reiterate that Lilly has no plans to discontinue the sale of purified pork insulin, even though its use is small and continues to decline. We will, however, continue educational efforts directed towards physicians and patients about the physiological advantages of human insulin and its analogs."***

So the good news is that at this moment in time Lilly says that they have no plans to discontinue pork insulin but we have to be aware that this actually means that the plans could materialise at any time.

The other parts of his statement about the proven benefits of human insulins, we have covered many times before and we all know that there is no evidence to show that they have any clinical benefits for patients over animal insulins. Lilly may feel it is their duty to 'educate physicians and patients about the benefits of human insulins', but this is just another way of saying we will continue to advertise these insulins and not pork insulin. As consumers I am sure that most of us want our education to come from trained qualified people who hopefully do not receive their education from pharmaceutical companies!

Laughter Is Good For You

We all know that laughter makes us feel better and this is because even for a few minutes, we are forgetting our troubles. So it appears that laughter improves our quality of life or does it? The research on laughter and it's effects is mixed and there is not that much of it. Some 'humour experts' believe that laughter actually stimulates the immune system to help to ward off infections and illness. There is research that shows:

- People who survive one heart attack are less likely to have a second if they have 30 minutes humour a day.
- Laughter has been shown to stimulate the levels of steroid chemicals in the blood that are associated with stress
- It has also been shown to improve the tolerance levels of pain.

However, the psychological aspects of humour are its best use. Often we use humour as a coping mechanism – it can defuses stress, humiliation, embarrassment and it can also help us to cope with pain. At the right time humour can be helpful even in awful situations but if used inappropriately it can be destructive.

The research into humour is not conclusive. For instance 40% of people with heart disease are less likely to laugh in funny situations than people without heart disease, so does this mean that humour prevents heart disease or that people with heart disease lose their sense of humour?

Research evidence or not, perhaps we should all carry on believe in what we have been told from the craddle, that laughter is good for us because it certainly helps to make the world seem to be a happier place.

Note: If you have access to the internet you can have your dose of humour regularly by visiting www.humormatters.com

Snippets

Daily Record, 12.7.01 - Talking toilet can diagnose medical conditions

A Cheshire company has invented a talking toilet that can diagnose pregnancies and medical conditions like diabetes. The Versatile Interactive Pan [VIP] has a built-in probe that can analyse urine and excrement for hormone and nutrient levels. It also has e-mail capability and can notify your doctor of any problems. It's been dubbed the Toilet of the Future and costs £5,000 and the makers, Twyford Bathrooms,say it could be on sale by 2006. It also uses voice recognition so it can adjust itself to suit children and disabled people, and it even tilts to become a urinal for men. According to Twyford Bathrooms the VIP's technology is not new. But they say what is pioneering is how the IT has been reproduced, into a toilet of all things and they maintain that it is ideal for people with health worries.

Driving Regulations for insulin treated people in Northern Ireland
From August 20th 2001, people with diabetes treated with insulin will be allowed to drive Category C1 vehicles [large vans and lorries between 3.5 and 7.5 tonnes] after a satisfactory individual medical assessment and evidence of good diabetic control. DVLNI will issue information packs to drivers who feel that they will be able to benefit from these changes and new drivers will have the benefit of being assessed on an individual basis.

Novo Nordisk wins legal battle over insulin market
Brazil, 21.8.01 - Novo Nordisk has successfully appealed against an earlier Brazilian court decision that imposed a 76.1% surtax on its insulin imports into Brazil. The original decision presumably was to try to restrict this importation when insulin can be produced within Brazil. Novo Nordisk won the appeal on the grounds that the charge could cause irreparable damage to the company. This seems a strange defence for Novo Nordisk when only a week earlier the Financial Times reported how well Novo Nordisk are doing compared to other pharmaceutical companies! They have 44% of the world market for insulin sales, described by the FT describe as 'captive and expanding'. Novo's defence in Brazil of irreparable damage hardly seems possible for such a successful company, unless of course they fear that other countries would follow Brazil's lead!

Left-handed people
Research recently published in Gut shows that left-handed people are twice as likely to suffer from inflammatory bowel disease as right-handed people. The authors are not sure why this should be but comment that previous studies have shown that left handers are more at risk of increased rates of auto-immune diseases such as asthma, diabetes, autism and migraine.

You Should Know!

Anti-cholesterol drug withdrawn from the market
Bayer, the well-known German pharmaceutical company has

voluntarily withdrawn their lipid lowering drug, cerivastatin from the market in every country except Japan. Cerivastatin, marketed as Lipobay in Europe and Baycol in the US, has been linked to 52 deaths and 1,100 reported cases of muscle weakness caused by a condition is known as rhabdomyolysis. This can be life threatening and is the destruction of muscle cells that are then released into the bloodstream. If people become aware that they are developing this muscle disease they can stop the drug and recover.

The people most at risk from Lipobay are elderly people on high doses and especially when used in combination with another cholesterol drug, gemfibrozil. Lipobay is one of the range of drugs called statins that reduce cholesterol. All statins have been linked to this side effect of muscle destruction but Lipobay has been linked to significantly more cases than its competitors. Other statins are on the market and within days of the announcement about Lipobay the manufacturers of some of the other statins, issued statements assuring the public of the safety of their statins. One company even took out full page adverts in three US papers offering people a month's supply of their anti-cholesterol drug FREE!

The FDA, the US drug regulatory body, say that there are no plans to strengthen the warnings on the other statins but people taking them who suffer muscle pain should visit their doctor to review their medication. But the European Medicines Evaluation Agency in London is taking a different stance and has announced that it will conduct a safety review of other statins over the next few months.

However, Public Citizen, the consumer advocacy group in the US, is preparing to petition the FDA to strengthen warnings on all statins and the Financial Times [24.8.01] reports that litigation has already started in the US that will cost Bayer an estimated $1bn in compensation.

Why does all this matter to us?
People with diabetes are at greater risk of heart disease and therefore if their cholesterol levels are higher than normal, they are quite likely to be receiving treatment with statins.

What are the symptoms of rhabdomyolysis?
Weakness, tenderness, fever, dark urine, nausea and vomiting.

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: ——————————————————————————

From Your Editor – Jenny Hirst

IDDT welcomes the submission of letters and editorial articles for consideration of publication in future issues of the IDDT Newsletter. The editor and trustees do not necessarily endorse any opinions or content expressed by contributors and reserve the right to refuse, alter or edit any submission before publication. No part of this publication may be reproduced in any form without the prior written permission of the editor.

Insulin Dependent Diabetes Trust
PO Box 294
Northampton
NN1 4XS

tel: 01604 622837
fax: 01604 622838
e-mail: support@iddtinternational.org
website: www.iddtinternational.org