Insulin Dependent Diabetes Trust

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Collapse led to Mother tragedy

Stafford Express and Star
February 4th 2000

A Willenhall woman died after a crash in which her diabetic son-in-law blacked out and lost control of the car in which they were travelling near Wolverhampton, an inquest heard.
Mr Fletcher was unable to remember swerving, ploughing across a roundabout at speed and shunting another car 20 metres along a grass verge, the inquest in Cannock heard yesterday.
Only after the car came to rest and Mr Fletcher took glucose tablets did he realise what had happened, he told police in an interview. Mrs Pratt died in hospital a week later.

Mrs Pratt and Mr Fletcher had been driving round for about two hours when he suffered a 'low' at about 6.30pm. PC Graham reading from a transcript of the interview with Mr Fletcher told how Mr Fletcher had found his blood sugar level to be low earlier in the day and took glucose tablets to raise it.

Two years earlier his doctors had changed his insulin to a type which gave him little warning that his blood sugar level was falling, the court heard. In the interview Mr Fletcher said 'I didn't get any warning. I was devastated afterwards that this had happened. I've lost my mother-in-law.'

The court heard that Mr Fletcher had had diabetes for 15 years and had never had his driving licence revoked. He had been unable to face driving since the accident and voluntarily handed his licence back. The coroner recorded a verdict of accidental death.

Woman denied funds for life-saving drugs

The Ottawa Citizen
Maria Cook
February 13th 2000
Ontario refuses to pay for insulin woman requires from Britain
A Nepean woman with diabetes is caught in a set of circumstances beyond her control that prevent her from getting the insulin she needs to keep her healthy and alive.

Liliane Nixon, 44, relies on beef-pork insulin, which was discontinued in November 1998 by drug maker Eli Lilly Canada. Synthetic insulin has become the norm but she cannot tolerate it. While Mrs. Nixon is allowed to import beef insulin from England, she can't afford it, and the Ontario drug benefit program will not pay for it. "We went to Mars and back" to get the Ministry of Health to fund it, said Bill Grant, spokesman for Ottawa West-Nepean MPP Garry Guzzo. No success.

It seems like a simple problem, but there are no bending of the rules in this unusual case. Mrs. Nixon, who is on a disability pension, gets her drugs covered by the provincial drug benefit program. But the program only covers drugs that are licensed for sale in Canada and therefore have met Canadian standards. The company in England, CP Pharmaceuticals, has not yet applied to sell in Canada because the market is too small. "We owe it to those who are part of the plan to use drugs that are deemed safe by Health Canada," said Dan Strasbourg, a Health Ministry spokesman.

The cost—about $1,800 for a year's supply—may not be an insurmountable problem for many people. But for Mrs. Nixon, whose household budget is $1,800 a month for a family of five, finding an extra $150 a month for insulin is next to impossible. Her husband, Doug, lost his job at a car dealership two years ago when her illness worsened and he booked off too often to look after her. He is now trying to start a small business.

"My God, this person has been through so much," said Mrs. Nixon's endocrinologist, Dr. Jan Braaten, of the Ottawa Hospital, Civic campus. "Everything in life has been taken away from her and the government says, 'Forget it. We won't help you.' Why can't the government be generous? She deserves some help. She doesn't want to die." Mrs. Nixon has enough animal insulin to last until the end of June. "It's very depressing," she says. "By next summer, I won't be around without my insulin. Without it, I can't live more than three or four days."

Mrs. Nixon has suffered many complications since being diagnosed with insulin-dependent diabetes at age 10. She has had three toes and part of her right foot amputated, had a kidney transplant and lost most of the vision in one eye. She has heart problems and uses a wheelchair. Scouts Canada last year gave her the Award of Fortitude, their highest citation for adults, for volunteer work in the face of great adversity.

Mrs. Nixon's problem is being played out against a background of debate over synthetic insulins and the diminishing availability of animal insulin. A U.S.-based Web site called compassionateuse.com is devoted to this issue. When synthetic insulin was launched in 1983, it was hailed as a dramatic improvement in diabetes care. Made with human DNA, the biosynthetics are the first insulins that are structurally the same as the kind the body produces and do not trigger the allergic reactions that animal insulins sometimes cause. "In properly conducted clinical studies there has not been shown anybody who can't use human insulin," says Dr. Loren Grossman, associate vice-president of clinical research for Eli Lilly Canada in Toronto.

But a small number of diabetics insist they do poorly on synthetic insulin or suffer potentially deadly side effects, the most serious of which is dangerous loss of the ability to recognize they are about to lose consciousness. Mrs. Nixon said she tried synthetic insulin nine years ago but went into cardiac arrest while using it. Dr. Braaten said it is possible the synthetic insulin caused the disastrous reaction, although it can't be proved. "A retrial of converting Mrs. Nixon to human insulin is unacceptable," Dr. Braaten wrote the drug program branch last October. (Eli Lilly still produces a pure pork insulin, but

Mrs. Nixon says it does not work for her.)

Dr. Braaten said he has about 15 patients who have had problems with synthetic insulin. “They complain about not being able to feel their blood sugar. They feel confused, faint without warning, have low energy and muscle pain.” But Eli Lilly’s Dr. Grossman said reports of dangerous side effects are anecdotal and have not been proven.

Dr. Andrew Farquhar, a family doctor in Kelowna, B.C., does not accept this. “Lack of evidence is not proof that the phenomenon does not exist.” Dr. Farquhar, a diabetic, tried synthetic insulin in the 1980’s but quit after he suffered low blood sugar one night and could barely get up for help. It raised the spectre of “dead in bed syndrome” in which a diabetic fails to experience low blood sugar symptoms, falls into a coma and dies from a seizure or heart failure. “I was scared,” he said.

Janis Booth, 47, a diabetic who lives in the Toronto area, tried synthetic insulin from 1993 to 1999. “I went from a healthy, active person to a semi-invalid.” She is negotiating with her insurance company to pay for beef insulin from England. If it’s not covered, she will pay for it herself. “I have no choice.”

Meanwhile, a Victoria, B.C., woman is setting up a Canadian chapter of the Insulin Dependent Diabetes Trust, a lobby group of animal insulin users that began in the U.K.
Carol Baker hopes to attract members and begin to lobby provincial drug programs for coverage. “It is a hardship issue,” she said. “We’ve been left out in the cold.”
Ms. Baker can be reached at: iddt_cda@yahoo.com or 604-608-3103.

Of the 1.5 million diabetics in Canada, about 10 per cent, or 150,000 are insulin dependent.
Of those, up to three per cent, or about 4,500 are still using animal insulins. Injected daily, insulin replaces a hormone usually produced by the pancreas for people whose bodies do not manufacture it naturally.

Note: The Ontario Ministry of Health did finally agree to pay for life-saving insulin for Mrs Nixon’s beef insulin to be imported from the UK

The key to GM is its potential, both for harm and good

By Tony Blair
Independent on Sunday
27 February 2000

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

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

Response from IDDT to Mr Blair and his ministers
GM Technology – potential for harm and good
I applaud the stance of Tony Blair and Mo Mowlam that GM technology

has the potential for both harm and good and that there is a need to proceed with caution. However, I was dismayed and angered to see that they cited insulin produced by GM technology as an example of potential good. At best the development of synthetic so-called ‘human’ insulin can only be classed as an example of the need to proceed with caution but it is also an example of the potential for harm.

Clearly Mr Blair’s advisers have failed to do their homework properly. If they had, they would have found that in an unidentifiable sub group of people it causes unaccountable adverse reactions. The symptoms fall into clearly defined categories of extreme tiredness, confusion, memory loss, behavioural changes and worst of all for people with diabetes, a loss of the warning symptoms that their blood sugar levels are falling resulting in a greater risk of severe hypoglycaemia leading to coma possibly with seizures. In addition to this, there have been reports of people being found dead in an undisturbed bed, a phenomenon that has become known as the ‘dead in bed syndrome’ and one that was unheard of before the introduction of insulin made by GM technology.

If Mr Blair’s advisers had contacted the DoH, they would have found that the number of reported adverse drug reactions [ADRs] for synthetic insulin far out numbers those for the natural insulins even though the ADRs for natural insulins have been collected for 14 years longer! They would have also seen that Baroness Hayman made a statement in 1998, under New Labour, that the Committee on Safety of Medicines had concluded that some people were not suited to synthetic ‘human’ insulin.
Perhaps of most concern is that people with diabetes who have reported these adverse reactions have not been listened to by their doctors or the insulin manufacturers. Their experiences are valuable evidence that should not be ignored, especially as synthetic insulin was the first drug to be produced by GM technology. They now face a situation where the two major suppliers of insulin in the world are systematically withdrawing natural insulins, so leaving these people without the necessary insulin that they need to remain healthy. We have been taken over by the gains of this technology but the gains are not for the consumers but the manufacturers. GM produced insulin has never been proved to have any clinical advantages for patients, it has not resulted in a reduction of cost, just the opposite and there is no shortage of the natural products to justify claims of shortages.
This all demonstrates that products from GM technology do not suit everyone and they can have unaccountable and unexpected adverse effects. People with diabetes have been battling for over 15 years for recognition of the problems that GM produced insulin can cause can cause in some people. Our Trust started with a few people but we are now international with branches in five other countries, showing that the problem is a global one.

Those that have suffered the consequences of treatment with insulin produced by GM technology would consider that Mr Blair should use this as an example of the potential for harm rather than the potential for good.

Note: No response was received from the Prime Minister or his office, despite three requests.

Independent on Sunday

Wobbling words are not enough
March 5, 2000

WHILE I applaud the stance of Tony Blair that GM technology has the potential for both harm and good and that there is a need to proceed with caution, I was dismayed to see that he cited insulin produced by GM technology as an example of potential good. At best synthetic so-called “human” insulin can only be classed as an example of the need to proceed with caution, but it is also an example of the potential for harm.

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Jenny Hirst
Insulin Dependent Diabetes Trust
Northampton

Possible unfair trade practices in insulin marketing

Health and Medicine, US
April 2000

NEW DELHI - Rising costs of insulin, a key drug for diabetics, and alleged attempts by multinational corporations to spread fears about unsuitability of using animal-derived insulin, which is cheaper, are hindering cost-effective treatment of a large number of poor diabetics in the country, an expert warned.

There is strong circumstantial evidence suggesting that unfair trade practices by one of three multinational companies (MNCs) selling insulin in India may be responsible for the price escalation, Dr. N. Kochupillai, head of the Department of Endocrinology and Metabolism in All-India Institute of Medical Sciences (AIIMS), said.

Disturbing news of the possible disappearance of bovine insulin (derived from animal pancreas) from the Indian market is of concern. While this may promote the sale of human insulin, which is three times more costly, it would jeopardize the survival of thousands of poor young diabetics, Kochupillai, a leading expert on endocrinology in India, said. Some MNCs have created an impression among doctors that use of bovine insulin may lead to insulin antibody formation in the body and related insulin resistance, leading to larger dose requirements, he said. Disproving this notion, Kochupillai and colleagues at state-owned AIIMS have, in a new study, found that antibodies formed with both human and bovine insulin treatment do not neutralize the effect of insulin due to low concentration and energy. The antibodies have no functional significance, he said.

The findings, which have been accepted by the British Journal Diabetes Research and Clinical Practice, would help arrest the increasing tendency among professionals to prescribe expensive human insulin, Kochupillai said. As most of the 2.5 million diabetics in the country, who constitute about one-tenth of the total Indian diabetic population, hail from the poorer section, insulin costs are becoming increasingly unaffordable for them, he said. The cost of bovine insulin (for 400 units) increased from Rs. 12 in the mid-80s to Rs. 76 now, while that of human insulin (derived by recombinant DNA technique) rose from Rs. 185 to Rs. 210 in the same period.

Diabetic Sues Over Insulin

Albuquerque Journal
New Mexico
8 April 2000

A class-action lawsuit against Eli Lilly and Co. and Novo Nordisk alleges the drug makers' biosynthetic insulin products can hurt diabetics. The lawsuit, filed last week in Federal court in New Mexico, also

contends the two companies have recklessly reduced the production alternative medications.

Rene Ostrochovsky, a lawyer handling the lawsuit for Roehl Law firm in Albuquerque, said Thursday it was too early to discuss the lawsuit. The lawsuit was filed on behalf of Suzan Kawulok, a diabetic from New Mexico. She wrote on a diabetes Web site that she took Lilly biosynthetic insulin, called Humulin, in 1987, and it caused “unbearable pain and loss of most use (of) my arms.” She went back to animal insulin then tried the biosynthetic version again in 1998 and experienced the same problems, she said. “It was the human insulin causing these horrible symptoms,” said Kawulok, who now takes pork insulin. Both types of insulin - the biosynthetic versions made from human DNA and the animal-based versions made from the pancreas glands of cows and pigs - help control blood sugar levels for diabetics.

The Indianapolis based Lilly and Novo Nordisk began marketing the biosynthetic versions of the drug in the 1980s. Since then, human insulins have gradually replaced animal-based insulins.
Novo Nordisk is based in Bagsvaerd, Denmark, just north of Copenhagen. In the past five years, Novo Nordisk stopped selling all its animal insulins in the United States and Lilly dropped its beef-pork mix, which was once the nation’s most-used insulin.

The only animal insulin left on the U.S. market is a pure pork product sold by Lilly.

The 18-page lawsuit says Lilly and Novo Nordisk ‘recklessly and maliciously discontinued or significantly reduced the manufacture of animal-based insulins knowing that diabetics had serious adverse symptoms” from the biosynthetic products.

The lawsuit also alleges the two companies failed to warn patients that human insulin can cause injurious, life-threatening symptoms, including arthritic syndromes and a lack of awareness of low blood sugar. It also accuses Lilly and Novo Nordisk of trying to prevent other companies from making animal-based insulins, and asks that the firms be ordered to release their formulas for animal-based insulins to another manufacturer. “We stand behind the safety of our drug,” said Lilly spokeswoman Doyla Chadwick. She said more than 3 million people rely on human insulin injections to live, and “the safety of human insulin has been proven by regulatory authorities almost 20 years ago. Human insulin is identical to the insulin produced naturally by the body. ...and is less allergenic than animal insulin.”

David Groves, a Birmingham, Ala., business consultant who runs an Internet discussion board on animal insulins, blames Novo Nordisk’s human insulin for his near-death in a car crash years ago. He called the lawsuit a good thing, but questioned how the law firm will identify plaintiffs who can point to human insulin as the cause of their health problems.
“The affected class has no way of knowing they’re affected. It took me years and years and two additional auto accidents to make me aware human insulin was the cause of my accident, and I’m no dummy.”

Rick Ewing, a Houston trial lawyer who has sued Lilly over its drug Prozac, predicted plaintiffs’ lawyers will have difficulty pursuing the New Mexico lawsuit against Lilly. “Lilly will be like an enraged bull elephant on this one,” Ewing said.

NHS FAILING DIABETICS – Audit Commission Report

A report from BBC News
UK, 12 April, 2000

Diabetes sufferers are at risk because of sub-standard care from the NHS, an official watchdog has warned. Patients face long waits for treatment, are not given vital information about their condition and face wide variations in the quality of care across the country,

according to the Audit Commission. Services are under pressure and in some areas patients are not getting access to the high quality care they deserve

There are 1.4m people diagnosed with diabetes in the UK and NHS spending on the condition is estimated at almost £5bn a year. Diabetes is the single biggest cause of blindness and the most common reason for lower leg and foot amputations among adults of working age.

The report found that half of patients already had serious complications as a result of diabetes by the time their condition was diagnosed. Some sufferers had to wait 14 weeks for a first appointment with a consultant after being diagnosed. A third of patients complained of long waits in clinics and said their privacy was not respected, being asked personal questions and weighed in open rooms. Two-thirds of patients said they had not received any support or education about their condition in the past year and a quarter did not know how diabetes is affected by illnesses such as cold or flu. A fifth had no idea what to do if their blood glucose levels dropped too low, which can cause coma or death.

The majority of sufferers have Type 2 diabetes, which can be controlled by diet and exercise, while Type 1 diabetes requires daily injections of insulin to control blood glucose levels. Around three-quarters of people with diabetes have their condition managed by a GP, but the report recommends that family doctors take more responsibility from hospitals.

Just half of health authorities had a district-wide screening service to prevent blindness and less than a third of GPs had regular access to a chiropodist to prevent problems which could in extreme cases lead to amputation. Without the proper care, people with diabetes are at risk of long term complications such as blindness, heart disease and kidney disease

Some hospitals have ten times as many consultants to deal with the condition as others, the report adds. The report calls for better training for staff and improved education for patients and improved links between different services such as chiropodists and dieticians.

Andrew Foster, controller of the Audit Commission, said: “Our study shows that services are under pressure and in some areas patients are not getting access to the high quality care they deserve. We believe that more routine care could be provided by staff outside hospital to a high standard, given proper support by specialist teams.”

Paul Streets, chief executive of the British Diabetic Association, said: “It is time that the gaps in the diabetes service provided by the NHS are dealt with. Without the proper care, people with diabetes are at risk of long term complications such as blindness, heart disease and kidney disease. It is unacceptable that everything possible is not being done to reduce this risk.”

He said people with diabetes should have a greater role in determining their care and more emphasis should be put on early diagnosis.

The government is set to produce guidelines on treating diabetes when it publishes a National Service Framework on the condition next year. A spokeswoman for the Department of Health said: “The report highlights unacceptable variations in the quality of diabetes services. If some local health authorities can provide first class care then all should be able to.”

Warning on human insulin legal cases

Pulse - Journal UK
By Caroline White
May 20, 2000

Legal action against human insulin manufacturers in the US could spark copycat cases in the UK, diabetes and legal groups have warned.

The comments came after it emerged that a patient with diabetes in New Mexico had started proceedings against Eli Lilly and Novo Nordisk, alleging that human insulin can cause lethal side-effects and

lowered hypoglycaemic awareness.

Under the proceedings started in April, around 80 allegations have been made, in 30 other potential cases, including failure to notify doctors and patients of potential side-effects, suppression of information, and inadequate trial data.

In the UK, the introduction of human insulin in the mid-1980s was followed by legal action in the early 1990s, but this petered out because of lack of medical evidence. But this new legal action in the US could spark renewed interest in the issue, according to Liz Thomas, assistant director of the charity Action for Victims of Medical Accidents.

'It may be that in the UK action could be brought on the back of the US proceedings, rather like the silicone implants case,' said Ms Thomas.

Ten 'major medical problems have been identified, according to Rene Ostrochovsky of the Roehl Law Firm, who is handling the US case. Publicity about the case has sparked a rash of calls from potential litigants. Around 30 other cases from across the US have been registered, with another 40 pending. The drug companies have until the end of May to respond. If a case merits a class action, the outcome of any final judgement in the US will apply to anyone affected.
No legal action is currently being brought in the UK, but a spokesman for the British Diabetic Association [BDA] said that it would be following the case in the US with interest. 'We do continue to receive a few complaints,' he said.

A spokeswoman for the Medical Defence Union said that datasheets for human insulin specify the potential for lowered hypoglycaemic awareness but GPs should take care to mention this to patients. Provided they did this, any legal claims in connection with human insulin would be directed against the manufacturers under product liability, she said.

Eli Lilly stopped manufacturing animal insulin in the US on commercial grounds. But Novo Nordisk has assured the BDA that animal insulin will not be withdrawn in the UK as long as there was demand.

GM medicine 'risks the lives of diabetics'

The Observer
Antony Barnett, Public Affairs Editor
Sunday May 7, 2000

The lives of thousands of British diabetics were put at risk by multinational drug companies that 'intentionally and maliciously' suppressed information about the potentially lethal side-effects of a genetically engineered medicine, according to claims in US court documents.
An American lawsuit launched in April against two drug corporations will embarrass Tony Blair, who this year cited synthetic insulin as an example of the benefits of genetically modified technology in producing 'life-saving medicines'.

Yet lawyers representing a victim of the man-made insulin in a class action case in New Mexico claim the genetically engineered medicine leads to 'confusion, distress, coma and even death'. The diabetic bringing the case, Susan Kawulok, said the product caused 'unbearable pain and loss of most use of my arms'. Although no evidence has yet been put to substantiate claims that the firms acted improperly, the case could send shock waves through the pharmaceutical industry, which has invested millions in genetically engineered products.

Diabetics do not naturally produce enough insulin - a vital hormone that controls the level of sugar in the blood. Hundreds of thousands of British diabetics have to inject insulin each day to survive. Until the Eighties, this insulin came from pigs or cattle, but US drugs giant Eli Lilly and a Danish company, Novo Nordisk, developed a synthetic insulin using genetic engineering. The new medicines were hailed as

a scientific breakthrough and branded as 'human' insulin to distinguish them from the animal-derived product.

Some 150,000 diabetics in Britain were switched to the new medicine and currently around 500,000 use these products. Although most diabetics have never had problems with the genetically engineered insulin, a significant minority have complained of serious side-effects. Unlike the case with natural insulin, some diabetics do not get any warning their blood sugar level has fallen and are more likely to go into comas, known as hypoglycaemic episodes or 'hypos'. Some become violent or pass out while driving.

In February, a diabetic, Mervyn Fletcher, crashed his car in Wolverhampton, killing his mother-in-law, a passenger. He blacked out and swerved, ploughing across a roundabout and shunting another car 20 yards along a grass verge. Only later when he took glucose tablets did he realise what had happened. Fletcher, a diagnosed diabetic for 15 years, had kept his driving licence. But two years ago his doctor had switched him from animal insulin to the genetically engineered product. At the inquest, Fletcher said: 'I didn't get any warning. I was devastated afterwards that this had happened. I've lost my mother-in-law.'

Last June Alasdair Padmore, a diabetic civil servant, stabbed his friend through the heart during a 'hypo'. He was cleared of murder because of his condition. He 'fought like a man possessed' with police when they tried to arrest him and told them he had no recollection of the incident.
Scientists defending man-made insulin claim there is no scientific evidence it presents a particular risk, and both Eli Lilly and Novo Nordisk deny it has harmful effects. But last year it emerged that the British Diabetic Association suppressed a report highlighting the problems of those using synthetic insulin. The report was never published in full because the association believed it was 'too alarmist'.

A spokesman for the British Diabetic Association said: 'We will be watching this case with great interest. It highlights the need for manufacturers to supply animal insulin for the many who need it to survive.'

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Pioneer surgery may end daily jabs or diabetes

Daily Mail
Wednesday 17th May 2000

A breakthrough in the treatment of diabetes by a British surgeon means hope for sufferers everywhere, it is claimed. They could be spared daily injections - and strict diets - following the successful transfer of insulin-generating cells into eight patients, say experts.
James Shapiro, who is currently working at the University of Alberta, Canada, carried out the pioneering technique. He extracted the cells from the pancreas of dead donors, purified them and then injected them into the trial patients through a main vein connected to the liver. From this site, the cells were carried into the liver where they "nested" and produced sufficient insulin for the patients to live without having up to 15 injections daily. Experts regard the successful transfer of the cells, called the pancreatic islets, as a highly significant advance.

Until now the only treatment option for the most serious cases of diabetes has been the transplantation of an entire pancreas, a major operation that does not always work.
Injecting the islets into the portal vein was a "simple procedure" Mr. Shapiro told the joint conference of the American Society of Transplant Surgeons and the American Society of Transplantation in Chicago.

Mr. Shapiro and colleague Jonathan Lakey purified the islets and kept them alive so they worked in the recipient even though they were functioning in a different organ.

The eight patients aged 29 to 53, all insulin-dependent diabetics since youth, were now "totally off insulin", said Mr. Shapiro. The first procedures were carried out 14 months ago. The recipients had very severe diabetes and often blacked out without warning. "They were crashing their cars, falling off horses or burning themselves while cooking", added Mr. Shapiro.
The patients now lived ordinary lives and showed 'complete control' of a chemical marker which signals damage from high blood sugar.

A new anti-rejection drug, Rapumune was key to the treatment, said Mr. Shapiro, who formerly worked in Newcastle upon Tyne and Bristol. He went on "the drug regime is extremely well tolerated. There has been clear and dramatic improvement in the quality of life for the patients and no evidence of rejection."

Mr. Shapiro, 38, who is to receive the prestigious Hunterian medal at the Royal College of Surgeons in London next week to mark his achievements in medicine, said the only potential problem was being able to provide the technique for the number of diabetics wanting it. Getting a sufficient supply of islets could be overcome in about five years by cloning techniques.

Eight transplant centres in the US and five in France are ready to try and duplicate Mr. Shapiro's work. Last night, Dr Richard Moore, clinical director of the transplant centre at University Hospital of Wales, predicted "enormous" demand for the procedure. He added, "This really is a breakthrough. Diabetes Mellitus is a very severe disease and most diabetics would jump at the chance to have a normal diet, avoid a regime where they need several injections a day, and constant monitoring of blood sugar levels."

Previous transplant attempts had failed because anti-rejection drugs often damaged the very organs they were designed to keep in place.

Launch of Insulin email discussion group

Misc. News Media
12th June 2000

A new email discussion group has been created for people who use insulin - in particular, for those who are not happy using "human" insulins. This forum allows members to discuss and share their problems and successes. In order to foster a friendly supportive environment, it is a "closed group". This means that members must apply to join. Their emails can only be read by other members of the group. A list of all other group members can be obtained at any time.
To read more about the Insulin discussion group, visit:
www.egroups.com/group/insulin

To join the group, send an email to insulin-subscribe@egroups.com
The administrator of the Insulin discussion group is John Neale jneale@webshowcase.net

Deaths associated with 'human' insulin omitted from review

News Release
Insulin Dependent Diabetes Trust
July 22nd 2000

Is it further suppression by the British Diabetic Association of information about 'human' insulin?

Two years after completion, a British Diabetic Association funded review of genetically engineered 'human' insulin and natural animal insulin has been published on their web site, but the original review has been changed to omit a section about deaths associated with 'human' insulin.

The review comparing ‘human’ and animal insulin was carried out and completed in July 1998 by the Cochrane Diabetes Group under Professor Rhys Williams, Nuffield Institute for Health, Leeds. It was presented in its entirety to the BDA Medical Conference in May 1999 including the section about deaths associated with ‘human’ insulin. This is now excluded from the review preventing this information being available to people with diabetes.

The following section from the original review has been omitted:

“The following observations can be made from this body of evidence:

- Increased frequency of hypoglycaemia and reduced awareness of impending hypoglycaemia do occur when people are transferred from animal to “human” insulin.
- In some cases (probably a small number) these phenomena may lead to death.
- It is not possible to determine, from the evidence available, how commonly these phenomena occur.
- From mortality data it is likely that any association with sudden death is uncommon.

It is not possible to say whether these phenomena are specific to “human” insulin or an effect resulting from tighter glycaemic control perhaps compounded, in some cases, by neurological complications in long standing-diabetes.”

Page 5 of ‘Human and animal insulin compared’, 29 July 1998

Alteration of the original review raises serious ethical questions and omission of the information about deaths associated with ‘human’ insulin, continues to leave people with diabetes in the position of not being able to make a truly informed decision about their insulin treatment.

- Why has the review been changed and who instigated the change?
- Has the review been changed at the instigation of the BDA who funded it? If not what evidence has changed since the review was completed and put in the public domain in May 1999?
- Why has it taken two years to publish the review and why now? During this two years animal insulins have been systematically withdrawn from many countries and Novo Nordisk have announced global withdrawal during this decade. Even though this review may be too narrow, earlier publication would have provided at least some evidence to assist patients in their attempts to obtain and maintain supplies.

The consumer based Insulin Dependent Diabetes Trust [IDDT], the only consumer group represented on the Cochrane Diabetes Group, believed that the review should be independently funded because of the controversy surrounding this issue for over 15 years. There was an unusual refusal to change the protocol, despite criticisms from those invited to comment on it, that the protocol was too narrow and did not include all the adverse reactions.

The BDA had already suppressed a report by Dr Natasha Posner carried out in the early 1990s showing that the adverse reactions were real and fell into a clearly defined group of symptoms. IDDT became suspicious and withdrew from all involvement with the review.

Statement from Jenny Hirst, Co Chairman of IDDT

“ We welcome the more positive stance from the BDA that animal insulin must remain available, but we fear that this view may well be too late to influence the three major insulin manufacturers.

It seems our initial suspicions about the Review were not unfounded, and the removal of the section about deaths is very worrying. My faith and trust in all those involved in this whole ’human’/animal insulin debate has sunk to unbelievable depths. We know that the data sheets have issued warnings about hypoglycaemia and lack of awareness since the early 1990s. Patients also know that hypoglycaemia can cause death.

As both Aventis and Novo Nordisk [ref1] have publicly admitted the

serious adverse effects to 'human' insulin, it seems that the reluctance to be honest about the problems with 'human' insulin may no longer rest with them. This is not a happy thought for people with diabetes. As people in the US are now being faced with denial of the insulin they need, they are taking legal action. IDDT has always hoped that this would be avoided. We had hoped that there would be enough respect for patients' experiences, a desire to establish the real extent of the problems with 'human' insulin and a desire to treat people with diabetes on the basis of evidence rather than mere unproven assumptions. But perhaps we were wrong. It is sad that it may be up to lawyers to enable people requiring insulin treatment to have full information on which to base their treatment options."

Co-incidentally on May 5th 2000, IDDT wrote to the Health Ministers, the Medicines Control Agency and the Committee on Safety of Medicines asking for guidance and information for doctors and patients as a result of new statements from insulin manufacturers, Aventis and Novo Nordisk. These referred to the adverse effects of 'human' insulin therapy, for the first time including worsening of retinopathy [ref 1]. No response other than acknowledgements from Lord Hunt and the Chairman of the CSM, has been received and therefore IDDT carried out its stated intention and widely circulated this information to doctors and healthcare professionals before informing people with diabetes through their Newsletter and web site on July 1st 2000.

For further information contact:
Ref 1

April 24th 2000, Aventis:
"Human insulin therapy may be associated with hypoglycaemia, worsening of diabetic retinopathy, lipodystrophy, skin reactions (such as injection-site reaction, pruritus, and rash), allergic reactions, sodium retention and oedema."

September 1999, Novo Nordisk:
"Historically, improving glycaemic control with soluble human insulin has been associated with an increased risk of hypoglycaemia."

School taken to court for banning diabetic boy from overseas visits

The Independent, UK
October 19, 2000

A grammar school that banned a 15-year-old boy from going on two foreign trips because he is diabetic is facing legal action. The case of Tom White, which is being brought against Clitheroe Royal Grammar School in Lancashire by the Disability Rights Commission, is the first of its kind.

Tom, who has had diabetes since he was nine, was barred from a water sports holiday in France after he had been offered a place and had paid his deposit. The school imposed the ban after Tom had a severe hypoglycaemic attack, which causes dizziness and sometimes a blackout because of low sugar levels, on a school trip in February. Stuart Holt, the head, also told Tom's parents he could not go on a German exchange visit, even though he is taking German at GCSE.

Tom's father, Malcolm White, aged 48, said: "Tom is devastated by the ban. It is totally unfair to stop him going on trips with his friends and other pupils because he has diabetes. We have tried every channel to get the school to change their minds but they have chosen to ignore the medical, educational and legal experts."

Bert Massie, chairman of the Disability Rights Commission, said: "It is blatantly unfair to ban Tom because he's had one severe hypo. A disabled pupil should have access to the same opportunities as everyone else." He said the case "highlights the urgency to put the education system squarely within the bounds of anti-discrimination law."

The commission, which is bringing the case under the goods and services section of the Disability Discrimination Act 1995, said the case raised a glaring gap in the law. Because legislation did not cover

education, action could be taken only over recreational holidays and not over the German exchange. Mr White said that Tom had suffered only one severe attack and had his diabetes under control. He had offered to pay for training about diabetes for the school's teachers but his offer had been turned down.

In a statement, the school said it resented the suggestion that Tom had been barred because of his disability. "We have taken students with a range of disabilities on trips and will continue to do so. However, if a student behaves in a way which endangers his or her health or wellbeing or in a way which reduces the level of staff supervision available for other students, then we may decide not to take that particular student. "This has nothing to do with disability: it is rather that we make a risk assessment and take into account previous behaviour to ensure the safety of all our pupils."

Taming the diabetes monster

Australian Financial Review
November 30, 2000

Rather than being defeated by his illness, Ron Raab has confronted it, met all its demands and made it work for himself and for countless others. He is a living example of how it is possible to become your own expert and thrive while many others in the same situation have either died or become seriously debilitated.

In 1957, at the age of 6, Raab was diagnosed with insulin-dependent diabetes, a condition he would have for life. Figures show that close to half of the people similarly diagnosed in the '50s have since died or suffer disabling complications such as blindness, amputation or kidney failure. Today, Raab is a fit and healthy family man who devotes his time to making sure people with diabetes in developing countries have access to life-preserving insulin.

Every week, thousands of people in the poorer areas of eastern Europe, Africa, Central America and Asia suffer a painful and slow death which could be prevented if they had proper access to insulin.

With a background in economics and statistics, Raab founded Insulin for Life Inc (IFL), which collects donated insulin and diabetes supplies and delivers them to places of need. In many developing countries insulin costs more than 50 per cent of the average annual income. This contrasts starkly with developed countries, where the price is heavily subsidised and usually costs below 0.3 per cent of the average annual wage. Raab says more than $US3.2 million worth of supplies have been delivered since 1986, a volume that would have kept 40,000 people alive for three months.

As a man who injects himself four times a day, Raab appreciates the need for a reliable supply of insulin. He tests his blood four or five times a day and adjusts his insulin intake. Watching his diet and timing meals to accommodate his jogging are other normal parts of his daily routine. "I've given the monster of diabetes all the attention it demands and turned it into a pussy cat," he says. "It's become a minor routine inconvenience in my life. But I'm diligent and well-informed. For 20 years, I worked at the International Diabetes Institute in Melbourne."
As a child, Raab felt lonely not knowing anyone else with the disease. At that time he was injecting himself with a glass syringe twice a day, and because self-testing and treatment were primitive, he suffered swings in blood sugar that made him weak and could even put him out of action for a couple of days.

Apart from a brief lapse at university in the 1970s, Raab has taken his diabetes seriously and no longer has complications that interfere with his life. While good blood sugar control effectively allows a diabetic to live a normal life, Raab says achieving this requires three things.
The first is accepting that you're in the driver's seat and that it is up to you to take control. The second is to master the steep learning curve so you're informed enough to experiment until you find the right formula. And the third is to have an unbroken dedication to the routine of remaining well. "Basically, you have to become your own expert. If

you don’t give it what it needs, diabetes will bite you badly.”

Last month, Raab was elected a vice-president of the International Diabetes Federation, which represents diabetes associations in 135 countries. This makes him an international spokesman for the disease. Of the 12 vice-presidents, three are Australian. The other two are Professor Don Chisholm of Sydney’s Garvan Institute of Medical Research and Professor Martin Silink of the Sydney’s New Children’s Hospital.

Raab is always working at the frontiers of treatment and, after a stint at the Diabetes Centre in New York, put himself on a low-carbohydrate, moderate-protein and appropriate-fat diet. Traditionally, diabetics are advised to eat a diet high in complex carbohydrates, but Raab says in the past two years, through this diet, his insulin dose has fallen by 45 per cent, he has lost 10 kilogrammes, his hunger has decreased, his blood sugars are close to normal 24 hours a day and he feels “fantastic”.

Professor Chisholm says there may be a number of reasons why Raab responded well to a low-carbohydrate diet, but such a diet would usually be relatively high in fat and could increase cardiovascular risk. He would not recommend it for the average person with diabetes.
Neither would Professor Paul Zimmit of Melbourne’s International Diabetes Institute, who says Raab is an extraordinary example of someone who has fought the long battle against diabetes, is on top of it and is helping others in the process.
But the diet question is open. Other diabetes experts, such as Associate Professor Paul Moffitt at the University of Newcastle, believe in a low-carbohydrate diet, providing it is not high in fat and is palatable.

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