



# Insulin Dependent Diabetes Trust

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## HEALTH Time Magazine

May 8, 2006

What do you do if they stop making medicine that you depend on?  
Dr Weill

### Your drug was discontinued

ELI LILLY was the last U.S. manufacturer of animal insulin, which is extracted from the pancreatic tissue of cows and pigs and has been used by diabetics for more than a half-century. Lilly stopped selling the drug in March, and its last batch expired April 1. From now on, it will sell only synthetic human insulin produced by recombinant-DNA technology. The problem, according to patient-advocacy groups, is that some people cannot tolerate synthetic insulin. They say patients

develop resistance to it or suffer adverse reactions that can be severe, even fatal. Such patients are few, but those few are angry, vocal and organized. They say they need animal insulin to maintain their health, and if it is no longer available in the U.S., their only option will be to get it abroad. But most insurance doesn't cover that, so those without resources would be abandoned to their fate. "I've got a few bottles left; says Joi Shaivitz, 47, an environmental researcher from Owings Mills, Md., who suffers from Type 1 diabetes. "If I don't get a new supply, I'm going to die."

In Britain, activist patients have joined together to create the Insulin Dependent Diabetes Trust (IDDT) a charity that maintains an informative website, [iddtinternational.org](http://iddtinternational.org). IDDT contends that as many as 10% of insulin dependent diabetics cannot tolerate synthetic insulin. The group offers lots of anecdotal evidence that animal insulin may be a better therapeutic option for some patients and argues that

genetically engineered insulin was allowed on the market on the assumption-not evidence- of its superiority. IDDT says no long-term studies have been carried out to compare synthetic and animal insulins and cites a 2002 review by the prestigious Cochrane Collaboration that found that what studies have been done used poor methodology.

Most doctors, however, believe synthetic insulin is the gold standard for treating Type 1 diabetes and consider the debate over animal vs. human insulin a nonissue. Dr. Richard Jackson of the Joslin Diabetes Center questions IDDT'S claims and says randomized studies comparing animal and human insulins have shown no additional benefit from using the animal product.

Meanwhile, the pharmaceutical industry has been developing insulin analogues, molecular variations of human insulin that are absorbed more predictably. The new products could be highly profitable, but I'm not convinced that they have significant advantages over animal insulin. I suspect drugmakers are dropping animal insulin because it is not sufficiently profitable. More money can be made from genetically engineered insulin and even more from fancy analogues. IDDT says patients with insulin-dependent diabetes should have a choice of therapies, and I agree. If the animal hormone disappears from the market, someone ought to make it available or cover expenses for patients forced to get it overseas. This is a story about insulin. But it raises larger questions about how much oversight the U.S. government has over pharmaceutical companies and what kind of safety net it can provide when any of us fall through the cracks. .

March 31, 2006

The last day animal insulin was sold by the only remaining U.S. manufacturer

### **Diabetes by the numbers**

- Of the 14.6 million Americans with a diagnosis of Type 1 or Type 2 diabetes, about 3.9 million rely on insulin.

- Estimated total annual cost of diabetes in the U.S. \$132 billion
- Average annual cost of insulin use for each patient: \$1,778
- Annual average health-care cost per diabetic patient: \$13,243, more than double the spending on non-diabetic patients

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## **Threat to diabetics as drug giant goes over to GM insulin**

**Daily Mail**

**Lucy Elkins**

February 14th 2006

Thousands of diabetics fear their lives could be ruined because the insulin they depend on is being discontinued by one of Britain's biggest drug companies.

Around 30,000 of Britain's 800,000 insulin-dependent diabetics use animal insulin derived from pigs or cows. However the UK's main manufacturer, Novo Nordisk, has announced it is to cease producing, pork insulin and concentrate on making more profitable genetically modified 'human' and 'analogue' insulins.

It means that from December 2007 there will be only one UK firm making animal insulin, and patients are anxious this may cause a shortage and fear they may be forced to use alternatives they can not tolerate.

Diabetics need insulin to prevent their blood sugar levels spiraling out of control. The vast majority use the genetically engineered forms without any problems.

But in a significant minority estimated to be at least 5% these have been linked to symptoms including weight gain, violent mood swings,

memory loss, joint pains, mental confusion, seizures and exhaustion.

Jenny Hirst of the Insulin Dependent Diabetes Trust, a patients' pressure group, believes corporate profits have been put before people's well being.

'For many of our members, it feels as if a noose is tightening' she says, 'They depend on animal insulin in order to lead a normal life. Leaving them with only one supplier puts them in a very vulnerable position.'

'There is no evidence that 'human' insulin is any better, but it is more expensive. It costs around £40 a phial Novo were only able to charge £6 a phial for pork insulin. They have put profits before our members' needs.'

Genetically engineered 'human' insulin started to replace animal insulin in the Eighties. It was made by adding the insulin producing human gene to E coli or yeast which produces the hormone rapidly.

The idea was that it would be closer to the human form than animal insulin and therefore more effective. It is also faster acting than animal forms.

By the end of the eighties, 80% of insulin users were switched over to the new forms. The vast majority had no problems, but some were not so fortunate.

The most commonly experienced problem is that people no longer get warning signs of an oncoming hypoglycaemic attack. This occurs when the blood sugar levels fall so low that the body runs out of fuel and without an instant source of sugar, sufferers are at risk of coma and death.

Normally diabetics get signals that this is about to happen, such as an irregular heart beat, shaking or a change in body temperature. However, a survey by Diabetes UK found that 5% of insulin dependent

diabetics who switched from pork to human insulin no longer had these vital warnings.

The Department of Health has acknowledged that the new insulins can create a problem for some people. In a letter last year, the Minister of State Jane Kennedy Wrote: 'The Department of Health fully accepts that some people are better suited to animal insulin and that animal insulin should continue to be made available.'

During the Nineties, hundreds of those who claimed to suffer adverse reactions on human insulin tried to take legal action against the drug companies but were unable to do so because of lack of medical evidence.

However, doctors admit that it does not work for all their patients. 'There are many different insulins available and what is indisputable is that some combinations work better for some people than others' says Dr Bill Lamb, a consultant paediatric diabetes specialist at Bishop Auckland Hospital, County Durham.

'The scientific evidence says one thing and personal experience another. I have treated people who have said that human insulin did not suite them. However, it should be recognized that some people in the past had problems with animal insulins. 'Having diabetes takes a huge commitment to personal management and I think it is vital that diabetics have a choice about which insulin works best for them, rather than the choice being made by big drug companies who want to maximize profits'.

The Department of Heath has given assurances that pork insulin will be available for the foreseeable future. Yet from December 2007 patients will be dependent on one small pharmaceutical company Wockhardt UK, for their animal insulin supplies.

In the U.S. and across much of Europe, animal insulin is no longer available, and patients fear the same may happen here.

Novo's supplies are expected to be exhausted by the end of next year, but the company claims the decision is rational. 'For a long time it has been economically unsound for us to continue to produce pork insulin,' says Novo Nordisk's managing director Viggo Birch.

'We have consulted with the Government and with Diabetes UK to ensure that the fact that we are ceasing production does not mean there will be a shortage of this form of insulin.'

However Diabetes UK said it was disappointed and concerned by the news. Chief executive Douglas Smallwood says: 'Doctors must ensure that they listen to the experiences and preferences of the patients to ensure that the move to a different insulin is both safe and effective.'

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## Injections turned me into a Zombie

**Daily Mail**

**Lucy Elkins**

February 14th 2006

Charity worker Beverley Freeman, 35, from Northampton, explains how her life was turned upside down when she switched to GM 'human' insulin.

One day I was sitting at my desk at school when, without warning, I passed out cold. Luckily a friend recognized I was having a hypo and quickly pushed a sweet into my mouth. Had she not done so, I might have fallen into a coma. It was a terrifying experience.

I had been diabetic since I was five, but I'd always had adequate warning that I was going hypo. I would feel slightly sweaty or get a tingly tongue. I would eat something and all would be fine.

What had changed? My insulin. Having been on insulin derived from pigs since my diagnosis in 1976, in 1984, when I was 13, my specialist suggested I switch to the human form. He said it was supposed to control levels of insulin better and that the risk of long-term complications, such as failing eyesight and poor circulation, were reduced. But almost instantly I ballooned by four stone. It was awful because it happened just as my friends were getting boyfriends. Eighteen months later, I had my first blackout. Then it started to happen every week. It ruined my life. I just didn't want to go out and I changed from being an energetic and sporty girl to lethargic and slow. My schooling suffered too. My dreams of university were dashed and I left school with no qualifications at 16.

Through all this I made regular visits to my GP, but we did not think of the insulin. He could tell there was something wrong with me, but could not find out what. He sent me for batteries of tests, but everything came back negative.

Then by chance, when I was 23, my mum met another diabetic who said she'd had similar problems when she changed her insulin from pork to human. She too, had found life unbearable.

My GP was happy to try me back on pork insulin and within days I felt full of energy for the first time in ten years. When I think back to the way I was, I shudder. I couldn't live like that again.

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