

Bigger than Viagra?

It sounds too good to be true: a drug to help you stop smoking, stay happy and lose weight. Roger Henderson on the accidental discovery of bupropion

Tuesday July 13, 1999

Guardian

Modern medicine still relies on chance and serendipity far more than it cares to admit. Viagra, the prescription drug phenomenon of the past two years, was originally developed as a treatment for heart disease and it was only when users reported their impotence was a thing of the past that the manufacturers realised they had created a golden goose.

If reports from America are to be believed, a new drug that has properties also discovered by accident may take the United Kingdom by storm next year, and could be set to rival the success of Viagra. If approved, it may also go some way in helping health professionals to achieve their goal of reducing the number of premature deaths in this country from heart disease, as set out in the recent department of health white paper on the health of the nation.

Originally developed as an antidepressant, the drug - bupropion hydrochloride - was licensed in the US three years ago under the name Wellbutrin. Its main marketing point was that it did not greatly interfere with sexual function, something most antidepressants are notorious for affecting.

During trials of the drug, and quite by chance, it was realized that people taking Wellbutrin were finding it far easier to stop smoking than those who were not using it. Early reports suggested that they were not craving for cigarettes as they normally did, and had fewer withdrawal symptoms on stopping their habit.

Once the the company involved, Glaxo Wellcome, had picked up on this aspect of the drug, it began further trials specifically looking at the effectiveness of the drug as an anti-smoking aid. The results of this comparative clinical study were published in the New England Journal of Medicine in March this year, and make for impressive reading.

Just under 900 smokers were involved, all of whom smoked at least 15 cigarettes a day. They were split into four groups - those taking a dummy pill or placebo, those taking bupropion, those using a nicotine patch plus a bupropion tablet, and those using a nicotine patch alone.

After 12 months, 15% of those on the dummy pill were still not smoking. This was only marginally worse than the 16% using only nicotine patches, but nearly 31% of smokers taking bupropion had stopped. The surprising statistic, however, was in the group using both patches and bupropion - a success rate of 35%, more than double the usual rate seen in smokers trying to give up.

Just as important, side effects appeared to be minor, with few people having to stop the drug because of them. A dry mouth and insomnia were reported by users, but little else. People with a history of seizures or eating disorders should not take bupropion, but otherwise most smokers will be valid candidates for such treatment, which is the first such non-nicotine prescription available.

This combination of effective results and low side effects led to the drug being licensed in the US as an aid to stopping smoking, under the name Zyban. This has now been prescribed to some 3m Americans, over 1m of whom have stopped smoking.

Some of these ex-smokers who had kicked the habit by taking Zyban appeared on the BBC Watchdog Healthcheck programme in March this year. One of them, Keith Webber, was quoted as saying: "I was thoroughly addicted to cigarettes, which seemed to be a part of me. Zyban does make it easier, does calm that irritability, it keeps you on a far more even keel in dealing with the world." Another recovered nicotine addict, Paula Covey, said: "As sure as I'm sitting here I will never have another cigarette - it's just a better life now."

Attempts are now being made to secure a licence across the EU, with the Dutch authorities taking the lead through the regulatory hoops. The drug could be available in this country early next year.

Rob Cohen, therapeutic and science communications manager of Glaxo Wellcome, says: "With success rates double that of nicotine replacement therapy, Zyban, upon approval from the appropriate regulatory authorities, will provide an effective weapon for many people in their battle against nicotine addiction.

"A combination of Zyban and the nicotine replacement patch has shown a small benefit over Zyban alone, but it should be remembered that it is the addiction to nicotine that drives us to smoke. If you can overcome this addiction without feeding it through another route then the longer-term chances of keeping cigarette-free may be increased."

The prospect of a new popular prescription drug arriving on the market will inevitably lead to much debate over funding, and the government will be keen to avoid another debacle like that over prescription of Viagra.

Costs are in the region of £2 per day, but as Clive Bates, director of Action on Smoking and Health (Ash) points out: "The big question here is whether the government will allow doctors to prescribe Zyban on the NHS at the normal prescription charge. If not, the market

could be severely limited. If they do allow it, then the demand could be enormous - of over 13m smokers in the UK, 70% would like to quit.

"I believe such treatments are extremely cost-effective because it is much cheaper to help people to quit smoking rather than pour money into the treatment of cancer or heart disease later in life."

Nicotine addiction is a medically recognised condition; more than 1bn people smoke worldwide, and 3m died from smoking-related conditions last year. The figure is expected to rise to more than 10m a year by 2025. Global sales of products to help smokers quit will exceed £500m this year, and a non-nicotine medicine may be welcomed with open arms by smokers who have repeatedly failed to give up using standard nicotine replacement treatments. And while at first glance such a treatment might appear to have a lower success rate than, say, Viagra, the large number of smokers means that there are still far more potential patients - of both sexes - who may benefit.

And there is a promising postscript to this story. At the same time as the trials of Zyban, an American psychiatrist - Dr Kishore Gadde from the Duke University in North Carolina - found that obese depressed women who were given the drug in its capacity as an antidepressant began to lose weight quicker than those not taking it, by a factor of about three.

Early trials showed this to be a consistent weight loss and the women reported they felt satisfied with smaller portions of food, so ate less. Although it remains unclear exactly why this should be the case, it is probably linked with the neurotransmitters that are responsible for the craving and reward cycle linked to eating.

"This is not a flash in the pan," says Dr Gadde. "These patients have continued with their weight loss over a year and there do not appear to be withdrawal symptoms when they stop taking the drug." Bigger trials will take place later this year, and this weight loss aspect of bupropion remains at an early stage of development, but there is already excitement in the pharmaceutical industry about it. A drug that works on depression and helps you stop smoking and may help you lose weight into the bargain? It sounds like a marketing dream.

But as the drug regulatory authorities continue their deliberations, it is probably only a matter of time before pleas for the next "wonder drug" are heard by British doctors. One thing can be sure though - decisions over who will get it and who will pay for it will be a headache for doctors, patients, and politicians alike.

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Dr. Gadde,

AP Radio is running something on the weight study. However, we missed the deadline to speak with them yesterday. Cooney Waters will gather all resulting stories (BBC, OnHeath, MedCast, AP) and I will send them to your office.

Also, we continue to contact reporters and will let you know as opportunities arise.

I'll be around until approx. 5:00 PM. Here's my cell phone # again, just in case you need me: 917-846-3859.

Thanks!!

Great seeing you

Joelyn



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The Times
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Can one pill ease depression,
 help you lose weight and stop
 you smoking? **Cella Hall** reports

Pls. fwd to Kishore
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 Thanks



Three in one: bupropion was first developed

Now that

A PILL that makes it easier to lose weight, reduces cravings for cigarettes and treats depression sounds too good to be true. Yet, astonishingly, research is accumulating which shows that an anti-depressant might be able to do all three.

The circumstances in which the pill's three effects were discovered are familiar. As with Viagra — developed to treat a heart condition and now prescribed for impotence — a medicine designed to treat one ailment has been found to have an unexpectedly useful side-effect, anti-depressant.

In this case, the drug is bupropion hydrochloride,

which was first licensed in America in 1988 to treat depression, under the trade name Wellbutrin. Its particular claim to fame is that it does not interfere with sexual function, a side effect of some other antidepressants.

During trials, it became clear, by chance, that people taking the tablets found it easier to stop smoking. They said that the craving for cigarettes was easier to cope with.

The manufacturer, Glaxo Wellcome, quickly set up more trials specific to giving up smoking. In the study, 822 smokers with a habit of at least 15 cigarettes a day took one of four options: bupropion, a placebo, a nicotine patch or a nicotine patch, together with the active drug,



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as an anti-depressant but it may be licensed in Britain for its anti-smoking properties early next year

is a wonder drug

Bupropion doubled people's chances of stopping smoking. After a year, 58.3 per cent of those on the drug and the patch had stopped; and 38.3 per cent of those on the drug alone, 18.4 per cent of those using the patch alone and 15.6 per cent of those taking the dummy pill had stopped.

In 1997, bupropion — now also called Zyban — was given a licence for use in America as an aid to giving up smoking; Canada quickly followed suit. Applications have been made for a European licence, and Holland, as the test country, is expected to grant a licence within months.

At this point, an American psychiatrist enters the picture. Dr Kishore Gadde, director of the multi-centre clinical

trials in psychiatry, Duke University, Durham, North Carolina, was treating a group of obese women and had put some of them on Wellbutrin, to help them with mild depression. These women lost more weight than those not taking the drug, so Dr Gadde set up a double blind trial — in which neither the women nor Dr Gadde knew who was taking what; 28 women took the drug and 28 did not.

They were all on 3,000 calories a day and their average weight was 220lb (35 stone 10lb). After eight weeks, women taking the drug had lost an average of 14lb compared with 31lb for the women taking the placebo," he says. "This is not a flash in

the pan. They have continued with their weight loss over a year. There do not appear to be withdrawal symptoms when they stop taking the drug.

"What the women tell me is that they achieve feelings of satisfaction with smaller amounts of food. They can eat one small piece of pie and stop. If they feel hungry later, they will eat another small piece, but no more."

One adverse side effect was a dry mouth. The drug is not advised for people susceptible to fits.

Dr Gadde is planning a much bigger trial this year and will report early findings to a conference in September. In the meantime, Glaxo Wellcome remains cautious about

bupropion's latest reported attributes.

No one is quite clear how the drug works with the quitters and the dieters, except that bupropion acts on dopamine, a neurotransmitter — a messenger chemical in the brain that is involved in the reward pathways.

A licence for bupropion as an aid to losing weight is some way off. There is no licence application for bupropion as an anti-depressant (Wellbutrin) in Western Europe, but as an aid to giving up smoking (Zyban) it could be licensed in Britain early next year. In America, Zyban costs about £2 a day. Whether it will be available on the NHS as well as on private prescription is another story.



WEIGHT LOSS: The Latest From the Lab

TRYING to keep track of the latest diet and weight-loss news can seem as exhausting as an abs class. So, here's a little help: a rundown of five studies that report on some winning ideas and one big loser. All were presented at the recent annual conference of the North American Association for the Study of Obesity.

Mix it up Even a smart diet has its limits. That's the opinion of researchers who tracked 742 dieters for a year. After 24 weeks, subjects had shed roughly 30 pounds, but then weight loss tapered off. Scientists aren't sure what caused the slump, but say you might beat it by switching diets after six months.

Move more It's a scary thought: A 30-minute workout may not be enough. A Brown University study suggests people must burn up to 2,800 calories a week to avoid gaining weight. That's equal to walking an hour a day—double the government's recommendation. The researchers urge people not to be discouraged, just to build on their good habits.

Eat your oats They could help you slim down. Three hours after heavy subjects ate 350 calories of oatmeal or cornflakes, they drank as much of a nutritional shake as they wanted. The result: Those who ate the oats sipped 40 percent less. Researchers suspect oatmeal's fiber helped people feel fuller longer.

A promising pill Bupropion is used to treat depression, but it might also curb appetite. Duke University researchers put 31 overweight women on a diet and gave them either the drug or a placebo. Eight weeks later, those taking bupropion had lost 6 percent of their body weight; the others lost 2 percent.

Chitosan a bust The ads say the supplement soaks up fat. But a Swiss study suggests otherwise. After participants chomped on burgers and fries, some took Xenical, a prescription diet drug; the rest used chitosan. Xenical prevented 40 percent of the fat from being absorbed; the supplement did nothing. "I don't know what chitosan does," says study leader Hans Lengsfeld. "But it's no fat blocker."

Publication Date: Thursday, May 20, 1999

Popular Glaxo drug effective as weight loss therapy

With just more than a handful of anti-obesity drugs currently on the U.S. pharmaceutical market, Glaxo Wellcome Plc could soon add to that group a drug it already markets for treating two other conditions.

In a study of 50 obese women between 24 and 51 years old, researchers found that 67 percent lost more than 5 percent of their body weight after treatment with Glaxo's bupropion and a 1,600-calorie diet; 15 percent of those taking placebo with the diet had the same outcome.

Additionally, researchers found that women treated with bupropion lost an average of 13.7 pounds of their original weight as compared with 3.4 pounds for those taking placebo.

"The drug group lost four times more weight than the placebo group," said Dr. Kishore Gadde, who presented the study data at the 152nd annual meeting of the American Psychiatric Association. "The results were much more exciting than we expected initially."

Glaxo Wellcome markets bupropion under the name Zyban for assisting in smoking cessation and as Wellbutrin for the treatment of depression.

"It's not indicated for weight loss," Gadde said. "Until we have results replicated in a large, placebo-controlled study, I'm not recommending it."

Gadde did say, however, that he thinks bupropion might be as effective as the other drugs on the market indicated for weight loss.

to a Harvard University study published in the October 6 issue of the Journal of the American Medical Association.

The study found that men and women who ate six servings of fruits and vegetables had a 31 percent lower risk of stroke compared to those who ate fewer than three servings a day. Each additional serving eaten per day lowered the risk of stroke by 6 percent, but eating more than six servings didn't have an impact.

The reduction in risk may be the result of chemicals found in certain fruits and vegetables that prevent blood from clotting in the brain.

The best foods are in the cabbage family: broccoli, cauliflower and bok choy. Broccoli had the greatest impact in lowering risk by 32 percent while vegetables in general only reduced the risk by 4 percent.

Also, leafy green vegetables and citrus juices were found to be particularly beneficial. In fact, having a daily glass of orange juice was linked to a 25 percent drop in the risk of stroke compared to 11 percent for other fruits.

Linda Van Horn, Ph.D., Registered Dietician and Professor of Preventive Medicine at Northwestern University says that, "Many people don't realize how easy - and fast - getting those [six] servings can be. It can be as easy as drinking a glass of orange juice in the morning, snacking on an apple in the afternoon and including a vegetable at dinner."

And if you absolutely don't want to eat your brussel sprouts, one to two glasses of alcohol a day can also reduce your risk of stroke, according to Dr. J.P. Mohr of the Columbia Presbyterian Center.

Aired September 20, 1999
Heartburn Treatment

For people who suffer from heartburn, a new, quick procedure provides relief so you can still eat your favorite foods.

Heartburn, or acid indigestion, is caused by Gastro-Esophageal Reflux Disease (GERD). GERD occurs when stomach acid flows back up into the esophagus caused by weak muscles where the stomach and esophagus meet.

Currently, diet and antacids are used to control mild heartburn but medications, which are expensive, may be necessary in more severe cases. Another option has been surgery which requires general anesthesia and a one to three day hospital stay. After small openings are made in the abdomen, part of the stomach is wrapped around the lower end of the esophagus.

The new treatment involves using surgical stitches during endoscopy, which is used to evaluate reflux symptoms. The stitches are supposed to tighten the area between the stomach and the esophagus to prevent heartburn. No incisions are made and the patient doesn't need anesthesia. The procedure lasts about 30 to 60 minutes.

The procedure is appropriate for people who suffer heartburn several times a week. It is currently being studied at six centers nationwide, none of them are in the tri-state area. For more information, contact: Mayo Clinic Cancer Center, 200 First Street SW, Rochester, MN 55905, (507) 284-2511.

Aired August 12, 1999
Anti-Depressant May Help Weight Loss

If you're trying to lose weight, a drug used to battle depression may also help battle the bulge.

Kishore Gadde, M.D., a psychiatrist at Duke University Medical Center, noticed that obese patients taking the anti-depressant Bupropion SR lost weight more successfully. He then studied 30 women who were overweight but not depressed

and found similar results.

"The people who received bupropion SR did four times better than those who received placebo," said Dr. Gadde.

After eight weeks, women taking the drug and eating a 1600-calorie diet lost four times more weight than women on a placebo. Women who completed the study and took the drug lost about 6 percent of their body weight compared to about 1.5 percent for women on a placebo.

The drug is marketed under the names Wellbutrin SR and Xyban. The only side effect so far seems to be dry mouth. It does not affect sexual function like other anti-depressant medications. The drug's long-term effectiveness on weight loss has not yet been tested.

It could take two years before the drug is cleared for use as a diet aid. Right now, some doctors prescribe it to help smokers kick the habit.

For more information, contact Rebecca Levine, Duke University Medical Center, Box 3354, Durham, NC 27710, (919) 684-4148.

Aired August 9, 1999

Exercise to Strengthen Immune System

Exercise builds muscle, fights obesity, and strengthens your immune system.

One of the ways exercise stimulates your immune system is to increase the number of infection fighting cells called natural killer cells.

But there can be too much of a good thing. Exercise physiologist Robyn Stuhr says exercising everyday or twice a day can lead to over training. She says over-training can be characterized by fatigue and exercise performance suffers.

The symptoms of over-training can be subtle. Stuhr says to give yourself recovery time, such as one to two days between each day of intense exercise.

Raising "Good" Cholesterol with Medication

People with cholesterol problems are often treated by their doctors to lower their "bad" cholesterol. But if your "good" cholesterol is not high enough, there's a new treatment to remedy that situation that could help prevent heart problems.

According to Dr. Henry Ginsberg, of Columbia Presbyterian Medical Center, normally about 70 percent of our cholesterol is LDL, or bad cholesterol, and about 30 percent is HDL. The HDL, or good cholesterol carries cholesterol away from the blood vessels to the liver where it can leave the body. Good cholesterol should be higher than 35 for men and higher than 40 for women.

An article in the August 5 issue of the New England Journal of Medicine confirmed that it is important to increase levels of HDL or good cholesterol if it's low. According to Dr. Hanna Bloomfield Rubins, of the Veterans Affairs Medical Center in Minneapolis, Minnesota, about 20 to 30 percent of people with heart disease have low levels of HDL cholesterol and normal levels of LDL cholesterol.

Researchers found that the inexpensive drug lopid was effective in reducing deaths from heart problems. Of the approximately 2,500 men studied, those who took the drug daily for an average of 5 years were 22 percent less likely to die from heart disease or have a nonfatal heart attack and 29 percent less likely to have a stroke. In addition to raising the HDL levels, it also helped reduce levels of the total cholesterol and other blood fats called triglycerides.



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LOSE WEIGHT & STOP SMOKING

By LEE BOWMAN



05-21-99

WASHINGTON — A drug already approved to combat depression and help people stop smoking has shown promise as a weight-loss tool in a small, preliminary study, researchers say.

Speaking during a meeting of the American Psychiatric Association here earlier this week, Dr. Kishore Gadde of Duke University said a small group of women taking bupropion hydrochloride lost four times more weight over an eight-week period than a group of women taking inactive pills. All the women were also on a relatively modest 1,500-calorie-a-day diet.

Gadde said tests with the drug, which is sold as Zyban as a stop-smoking aid and as Wellbutrin for depression, are continuing, and that the women who responded during the first eight weeks appear to be losing additional weight as they continue taking the drug more than six months out, although the researchers haven't completed analyzing their data.

"While we have to approach the results cautiously because the long-term results are not completed, we are very excited about the potential this drug has for treating obesity," Gadde said.

The psychiatrist first noticed that the drug seemed to have an effect on weight among a group of women he was treating for mild depression at a Duke diet and fitness center.

Studies done before and after the drug was approved by the Food and Drug Administration as an anti-smoking aid in 1997 also noted that people taking the drug gained less weight as they quit smoking than ex-smokers taking a placebo pill. Tests showed that up to twice as many people on the drug quit smoking as those taking a placebo.

Features

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Gadde then approached the drug's manufacturer, Glaxo-Wellcome, with a proposal to test the drug's weight-loss properties on a group of non-depressed women weighing an average of 222 pounds.

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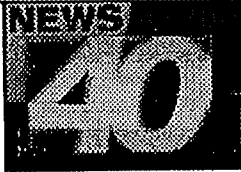
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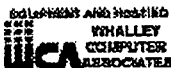
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Anti-Depressant Diet

BACKGROUND: Ninety-seven million Americans, or 55 percent, are considered overweight according to guidelines from the National Institutes of Health. The new standard is based upon a person's body mass index (BMI) -- a way of measuring body weight in relation to height and body fat. This puts them at increased risk for diabetes, heart disease and stroke.

WEIGHT LOSS HELP: A drug currently approved to treat depression and help people quit smoking has shown promise as a potential weight-loss tool. Kishore Gadde, M.D., of Duke University Medical Center realized overweight psychiatric patients in the anti-depression drug were able to lose weight easier and more quickly than those not on the medication. Dr. Gadde began a study to see if the drug could help non-depressed overweight patients lose weight. The average weight of women in the study was 222 pounds. In the first eight weeks of the study, women who took the drug combined with a 1600-calorie a day diet lost four times more weight than women on a placebo. The average daily caloric intake for a woman is about 2100 calories. At the end of the eight week study, those who completed the study and took the drug lost 6.21 percent of their body weight compared with a 1.56 percent weight loss in the women on a placebo.


HOW IT WORKS: Bupropion SR works by increasing available amounts of norepinephrine and dopamine in the brain. The two chemicals are believed to play a role in the reward and pleasure pathways. The drug marketed under the names Wellbutrin SR and Xyban. Dr. Gadde says its unique mechanism of action may account for why patients report bupropion SR does not suppress their appetite. Instead they report feeling satisfied more easily. Bupropion SR is not approved by the FDA for weight loss and is not recommended for use by patients with seizure disorders, anorexia or bulimia. The study will continue for another 18 months. A larger, multi-center trial is planned for the future.

SIDE EFFECTS: The only known side effect from Bupropion SR is dry mouth. Unlike other medications used for depression, it does not affect sexual function. They have not yet tested the drug's long-term effectiveness on weight loss.

OTHER USES: Bupropion is also currently being studied for its effectiveness in relieving nerve pain called neuropathy which can be caused by a number of factors including disease or injury.

FOR MORE INFORMATION, PLEASE CONTACT: Rebecca Levine
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Daily Mail

TUESDAY, JUNE 15, 1999

Is this anti-depressant a new weight-loss drug?

A DOCTOR has stumbled on a new anti-obesity drug which could become the world's most effective weight-loss treatment. The drug, Bupropion, is designed to treat depression, but when given to clinically obese women they rapidly shed pounds.

Now the British drug company which developed it is considering launching the anti-depressant as a treatment for obesity.

Patients on Bupropion have achieved weight loss equal to and greater than patients on the new anti-obesity drug Xenical, which was launched last year. Dr Kishore Gadde, a psychiatrist at Duke University Medical Centre in North Carolina, prescribed Bupropion for mild depression while helping women to lose weight at the university's fitness centre. Dr Gadde found that the women were losing significantly greater amounts of weight than on previous visits to the centre. 'I was amazed, because there had been nothing published about this drug having the ability to help weight loss,' he says.

As a result of his discovery, Dr Gadde persuaded Bupropion's manufacturer, Glaxo-Wellcome, to support a trial. 'I wanted to see if the drug would work under proper trial conditions, using a double blind test, because it was possible that what I had observed may have been a fluke.'

The results of a two-month study involving 18 women with an average weight of 16 stone proved the original findings were no mistake. After eight weeks on a diet of 1,600 calories a day, the women had lost up to a stone — 6 pc of their body weight. Women given a placebo lost 1.5 pc of their body weight.



New drug help for slimmers

Dr Gadde says: 'These women, who were significantly overweight, were able to achieve a good weight loss over a short period of time. A lot of them said the drug did not suppress their appetite but helped them feel satisfied more easily.' Bupropion acts in a different way to other anti-depressants, working on two brain chemicals, norepinephrine and dopamine, which are both implicated in the reward and pleasure pathways in the brain. 'This probably explains why patients say the drug helps them feel more satisfied while not suppressing their appetites,' says Dr Gadde. Although it isn't yet licensed to treat obesity, Dr Gadde expects other doctors will try it out experimentally. 'The important thing is that there are no significant side-effects, apart from a feeling of a dry mouth.'

MARTYN HALL

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Headline: **NEW DRUG THAT COULD BE BIGGER THAN VIAGRA**

By ROGER HENDERSON The Guardian

LONDON - Modern medicine still relies on chance and serendipity far more than it cares to admit. Viagra, the prescription drug phenomenon of the past two years, was originally developed as a treatment for heart disease and it was only when users reported their impotence was a thing of the past that the manufacturers realized they had created a golden goose.

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Originally developed as an antidepressant, the drug bupropion hydrochloride was licensed in the U.S. three years ago under the name Wellbutrin. Its main marketing point was that it did not greatly interfere with sexual function, something most antidepressants are notorious for affecting.

During trials of the drug, and quite by chance, it was realized that people taking Wellbutrin were finding it far easier to stop smoking than those who were not using it. Early reports suggested that they were not craving for cigarettes as they normally did, and had fewer withdrawal symptoms on stopping their habit.

Once the company involved, Glaxo Wellcome, had picked up on this aspect of the drug, it began further trials specifically looking at the effectiveness of the drug as an anti-smoking aid. The results of this comparative clinical study were published in the New England Journal of Medicine in March this year, and make for impressive reading.

Just under 900 smokers were involved, all of whom smoked at least 15 cigarettes a day. They were split into four groups - those taking a dummy pill or placebo, those taking bupropion, those using a nicotine patch plus a bupropion tablet, and those using a nicotine patch alone.

After 12 months, 15 percent of those on the dummy pill were still not smoking. This was only marginally worse than the 16 percent using only nicotine patches, but nearly 31 percent of smokers taking bupropion had stopped. The surprising statistic, however, was in the group using both patches and bupropion - a success rate of 35 percent, more than double the usual rate seen in smokers trying to give up.

Just as important, side effects appeared to be minor, with few people having to stop the drug because of them. A dry mouth and insomnia were reported by users, but little else. People with a history of seizures or eating disorders should not take bupropion, but otherwise most smokers will be valid candidates for such treatment, which is the first such non-nicotine prescription available.

This combination of effective results and low side effects led to the drug being licensed in the U.S. as an aid to stopping smoking, under the name Zyban. This has now been prescribed to some 3 million Americans, over 1 million of whom have stopped smoking.

Attempts are now being made to secure a license across the EU, with the Dutch authorities taking the lead through the regulatory hoops. The drug could be available in this country early next year.

Rob Cohen, therapeutic and science communications manager of Glaxo Wellcome, says: "With success rates double that of nicotine replacement therapy, Zyban, upon approval from the appropriate regulatory authorities, will provide an effective weapon for many people in their battle against

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Wellbutrin Makes Them Thin And Happy

A psychiatrist who noticed his depressed patients were losing weight may have stumbled across a new diet drug.

Kishor Gadde, M.D., of Duke University Medical Center, Durham, NC, led a team of researchers who examined the effects of Wellbutrin (bupropion SR, Glaxo Wellcome), an antidepressant, on 31 overweight women. Study participants weighed 222 pounds on average.

After eight weeks of treatment and a 1,600-calorie daily diet, the 18 women on the drug lost more than six percent of their body weight, four times more than 12 women who received a placebo. The treated women received a maximum of 200 mg of bupropion daily. Gadde reported his results in May at the American Psychiatric Association meeting in Washington, DC.

The study was funded by Glaxo Wellcome. Gadde cautioned that bupropion, which is also marketed as Zyban for smoking cessation, is not approved by the FDA for weight loss. The main side effect noted was dry mouth. —DAN VERGANO

Drug may help folks be happy, lose weight and stop smoking

255 713
SCRIPPS HOWARD

FRONT PAGE

WASHINGTON — A drug already approved to combat depression and help people stop smoking has shown promise as a weight-loss tool in a small, preliminary study, researchers say.

Speaking during a meeting of the American Psychiatric Association here earlier this week, Dr. Kishore Gadde of Duke University said a small group of women taking bupropion hydrochloride lost four times more weight over an eight-week period than a

group of women taking inactive pills. All the women were also on a relatively modest 1,600-calorie-a-day diet.

Gadde said tests with the drug — which is sold as Zyban as a stop-smoking aid and as Wellbutrin for depression — are continuing, and that the women who responded during the first eight weeks appear to be losing additional weight as they continue taking the drug more than six months out, although the researchers haven't completed analyzing their data.

"While we have to approach the results cautiously because the long-term results are not completed, we are very excited about the potential this drug has for treating obesity."

The psychiatrist first noticed that the drug seemed to have an effect on weight among a group of women he was treating for mild depression at a Duke diet and fitness center.

Previous studies noted that people taking the drug gained less weight as they quit smoking.

GDR177-0419


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MEDICAL BREAKTHROUGHS

reported by IVANHOE BROADCAST NEWS, INC.

ANTI-DEPRESSANT DIET #1460
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Imagine taking a pill and POOF! Your hunger goes away. The pounds melt off. Best of all, you feel great, not anxious like with some appetite suppressants. That's what doctors are finding by using an old pill a new way.

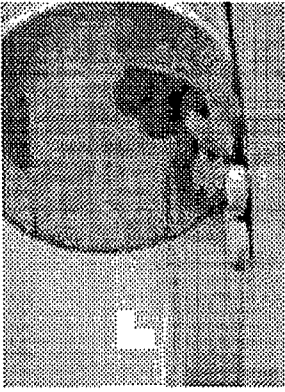
Jan Lucas has dropped five dress sizes in one year. "I weighed 217, and now I weigh 145," Jan says. She did it by eating 1,600 calories a day, just slightly less than average for most women. However, she also took an anti-depressant pill called bupropion SR.

Before long, Jan knew this diet would be different. "Other times when I lost weight, I really wanted to eat more food," she says. "I was never satisfied. Now, I feel like it's the answer to my prayers. I just don't have the cravings."

Kishore Gadde, M.D., a psychiatrist at Duke University Medical Center in Durham, N.C., came up with the idea after he noticed obese patients taking the anti-depressant lost weight more successfully. He studied about 30 women who were overweight but not depressed.

Dr. Gadde reports, "The people who received bupropion SR did four times better than those who received a placebo."

After eight weeks, women taking the drug lost an average of 14 pounds. Those on a placebo lost



only three-and-a-half pounds. The drug triggers the release of dopamine and norepinephrine in the brain. "It's a brain chemical or a brain hormone we normally associate with pleasure feeling," says Dr. Gadde.

He hopes more studies will show why the drug is so helpful to dieters. Jan remains in the study counting calories and loving her new look. "I feel like I can do this for the rest of my life," she says.

So far, the only side effect of the drug seems to be a dry mouth. It could be two years before the drug is cleared for use as a diet aid. Right now, many doctors prescribe it to help smokers kick the habit (Zyban).

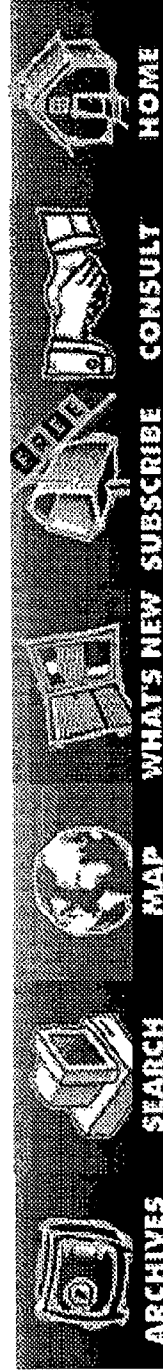
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Feel good, quit leaf — & get thin with drug?

By JIM SHAMP
The Herald-Sun

If you're depressed about the idea of gaining weight when you quit smoking, Glaxo Wellcome Inc. may have just the drug for you.

Glaxo's drug bupropion, sold as Wellbutrin SR for treating mild depression and, in a different form as Zyban to help people quit smoking, may have yet another life as a weight-loss agent.

Duke University Medical Center psychiatrist Kishore Gadde unveiled results of a preliminary study Tuesday in Washington, D.C., showing that women taking the drug while maintaining a 1,600-calorie-a-day diet lost four times more weight than women eating the same amount while taking a placebo — a pill that looks the same but contains no medicine.

His presentation to the American Psychiatric Association marks only the latest in a series of findings that could lead to a third new indication for bupropion, an old Burroughs Wellcome drug that has found financial legs since Burroughs was taken over by Glaxo Inc. in 1995.

Doctors initially noticed that depressed smokers trying to kick the habit had impressive results when taking Wellbutrin. Research studies ensued, resulting in the introduction of the drug as Zyban. A study published in the New England Journal of Medicine has since shown that 30 percent of smokers who took Zyban were able to quit and stay tobacco-free — double the percentage who quit with a placebo.

Similarly, physicians have been noticing weight loss seems easier for people using some form of the medication. Now, the Duke study is taking it a step further.

Gadde said he got the idea for his study while consulting at the Duke Diet and Fitness Center. He noticed when he gave patients the drug to treat mild depression, they lost more weight than usual.

So, he approached Glaxo with a proposal to test Wellbutrin SR in a group of 50 non-depressed women weighing an average of 222 pounds. He said he chose the 1,600-calorie diet because it's only 500 calories below an average

SABERING TI



With the line of hopeful ticket purchasers behind them, Jon Tofte (above, left) and Jesse Stewart duel with lightsabers Tuesday morning in front of the Wynnsong Theatre in Durham. Both spent the night in front of the theater to get tickets for "Episode 1 — The Phantom Menace."

Tickets went on sale at noon for the midnight and 3 a.m. showings Wednesday. Ross Haswell of Durham reads a book while waiting in line for tickets to the new Star Wars movie.



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FROM C1

woman's daily intake, so it would be safe and tolerable.

"It was designed to quickly get an answer," he told The Herald-Sun. "We wanted to figure out whether it was worthwhile doing a large study. The results were obviously very positive."

Of the 50 women who started, 25 were assigned to receive the placebo and 25 to get bupropion. Only 31 completed the full eight weeks of the initial trial, in which participants kept diaries logging their food intake. Women receiving the drug were given up to 200 milligrams twice a day, considered the maximum dosage for treating depression.

"In weight-loss studies, if people aren't losing weight, it's hard to keep them in the study," said Gaddé. "We asked those who dropped out why they didn't finish. We found that 32 percent in the placebo group dropped out because they were dissatisfied with their results, compared with only 4 percent in drug group."

Of the women completing the study, those getting the drug lost an average of 14 pounds, compared with an average loss of only 4½ pounds in the group receiving placebo.

Of those receiving the drug, 12 out of 19 — 67 percent — completed the study, compared with only two out of 13, or 15 percent, of those receiving placebo.

Another significant finding, Gaddé said, was that bupropion was tolerated "remarkably well, with no significant side effects."

Only one of the women in the study was a smoker, he said.

"Now we are going to do more large-scale studies," said Gaddé. "At this point it looks very promising. We'll be releasing results of our six-month evaluation phase very soon. All we can say at this point is that the 18 women who are continuing the study seem to continue losing weight. It's such an objective measure we can't really hide it."

Only women who lost 5 percent of their initial body weight, or four kilograms, in the first eight weeks, qualified for continuation in the study, said Gaddé. Though they're all continuing to lose weight, he said he doesn't know how many are receiving the drug and how many are on placebo.

"We tried not to take away something that benefited them, whether it was placebo or drug," said Gaddé. "But if they failed to benefit adequately in the first eight weeks, we offered them the chance to cross over to the other medication in the double-blind trial. If they respond to the crossover treatment in the second eight weeks, they'll be able to go into the next phase, for up to two years, as responders. But we're blinded to the treatment. Only the pharmacy knows what they're getting."

The researchers used body composition scans, called DEXA scans, to measure the women's percentage of fat and muscle loss.

"When you lose weight on a balanced diet you lose approximately

three-fourths fat and one-fourth lean mass, or muscle," said Gaddé. "But when you fast, you lose half fat and half lean mass. That's why fasting is not a good way to lose weight, because you lose a lot of lean mass."

The DEXA scans at the beginning of the study will be repeated after six months of treatment, at the end of one year and at the end of two years, to evaluate the quality of weight loss in the participants, said Gaddé. The scientists are also looking at bone mass density, because women who lose weight also lose a certain amount of bone mass, increasing their risk of osteoporosis.

Gaddé said many participants reported feeling pleasure after eating smaller amounts of food. They didn't say they felt full, just satiated, said Gaddé.

The researcher said the drug's effect is possibly related to brain chemicals, the apparent dopamine-enhancing and norepinephrine-enhancing effects of the drug.

"These neurotransmitters modulate pleasure and reward behaviors in the brain," he said. "But the mechanism is not well understood."

These neurotransmitters are also known to affect energy expenditure, he noted. Energy intake is the food we eat, while its expenditure is how calories are burned. Gaddé projected that the drug helps people reduce their desire for intake, while also helping

them burn calories more efficiently.

Unlike fenfluramine and dexfenfluramine — Fen-Phen, the diet drug which was withdrawn from the market over safety concerns, bupropion appears to have no effect on the neurotransmitter serotonin, said Gaddé.

The patent on the original bupropion formulation introduced in 1989, Wellbutrin immediate release, expired in 1994, though sales continued. The sustained release formulation, Wellbutrin SR, introduced in 1996, boosted sales of bupropion beyond \$200 million in 1997 alone. Zyban, approved in 1997 as the first non-nicotine product to help smokers quit, generated another \$52.5 million in sales during its first six months on the market.

Pharmaceutical analyst Edmund Debler has projected that sales of the three versions could reach \$300 million by the end of this year.



because of the 2,000-foot zoning. Brough told the Herald-Sun April, when the suit was filed. The city's ordinance violates the Amendment for two reasons.

First, the government cannot late adult entertainment because a form of speech under Constitutional protection, he said.

Second, the City Council zone adult businesses simply because it doesn't like them, he said. The city can only consider the "secondary facts" of adult businesses and land-use decisions based on the facts.

But Brough, considered an expert on land-use law, said city officials not conduct any studies to determine whether adult establishments affect the character of the neighborhood when they included an adult provision in the 1993 zoning code.

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A pill for all that addicts you?

Monday, 17 September 2001 20:43 (ET)

A pill for all that addicts you?
 By PEGGY PECK, UPI Science News

CLEVELAND, Sept. 17 (UPI) — A medication called bupropion, better known as Wellbutrin or Zyban, is generating a lot of buzz because it looks a wonder drug that can help people lose weight or stop smoking. The buzz is especially interesting because the drug initially was approved to treat depression.

So does this mean that depression, overeating, smoking and maybe other addictions like drug abuse or alcoholism are all somehow linked? The answer, say addiction experts, is maybe.

When smokers light up a cigarette and down a lung-full of smoke, nicotine triggers the release of a chemical called dopamine in the brain. Dopamine, in turn, acts on the pleasure center of the brain, which sends out those waves of pleasure that longtime smokers describe.

Likewise, dopamine is released when eat. "You know you've eaten enough when you feel full or sated," Dr. Kishore Gadde of Duke University told United Press International. But obese people often need to eat large amounts of food — in fact need to over-eat — to release enough dopamine to feel sated. "They may actually need higher levels of dopamine," he said.

People who are depressed, on the other hand, cannot get that dopamine high from smoking or eating or any other know dopamine triggers. Their dopamine levels remain so low they are incapable of feeling pleasure. That is where bupropion comes into the picture. It also regulates the release of dopamine.

When depressed patients take it, many of them start to feel better. But smokers and overeaters do not have to be depressed to get a benefit from bupropion.

Bupropion is not approved for use in treating other addictions, including alcoholism.

But by taking the drug, the smoker may not feel the need for the nicotine rush and the overeater may be able to push away from the table having consumed fewer calories.

There are several studies indicating the drug is an effective aide for both weight loss and smoking cessation, but addiction specialists are cautious about looking "for a cure in a bottle," said Dr. Howard Rankin.



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UPI News Article: A pill for all that addicts you?

Rankin, an adjunct professor of psychology at the University of South Carolina School of Public Health in Columbia, told UPI it does appear there "is probably a general addiction pathway in the brain," but he questions the wisdom of taking that road.

He said anyone battling an addiction, whether it is overeating or alcoholism, is "very good at looking outside themselves for both the source of the problem and a possible cure." He said that "magic bullet approach" usually is doomed because the affected individual fails to make the needed life changes associated with long-term recovery.

Those changes include a commitment to a "total life change and to ongoing support," Rankin said, and added it can be a 12-step program or professional counseling.

Dr. Tony Tommasello of the University of Maryland at Baltimore, told UPI that drugs like bupropion appear to work best when taken in conjunction with ongoing counseling or support programs. Moreover, a pharmacologic approach to treating addictions is probably most useful in "getting people over the initial difficulties like the physical withdrawal from nicotine."

Tommasello said most long-term recovery is linked to the type of lifestyle changes advocated by Rankin. "In the case of a recovering alcoholic, for example, recovery often turns on the ability of the alcoholic not to resist the urge to drink but to act on that urge in a positive manner, for example by going to an AA meeting," Tommasello said.

But Dr. James Taylor-Hayes, of the Mayo Clinic in Rochester, Minn., said maybe part of the total lifestyle change Rankin and Tommasello advocate should include lifelong medication to treat the addictive disorder. He has been studying efficacy of long-term bupropion treatment lasting a year or more to prevent relapse among former smokers.

Hayes said the bupropion is well tolerated with only a very minimal risk for seizure, and that risk is only seen in people who had a history of head injuries.

Many conditions, for example diabetes or high blood pressure, require chronic treatment with medications. But addictions, according to the experts, are not equivalent to illness like diabetes.

To illustrate, Rankin pointed to the anti-drinking drug called antabuse, which will cause one to become violently ill if taken in combination with alcohol. "I remember a treatment program where we were implanting antabuse under the skin in the arm and I saw people actually digging it out so they could drink. Chemical police just don't work."

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MEDICAL NOTES

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WATER is vital for life yet most of us don't drink enough of it. A new study has found that two thirds of Britons are dehydrated. The survey, by Robinsons, found that most people don't know they should drink at least eight glasses (four pints) of water every day.

PSORIASIS is one of the most common skin complaints and can be a very distressing condition.

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DO you have control of your drinking or does alcohol control you? If you regularly wake up with a hangover...

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... AND THEY DISCOVERED IT BY ACCIDENT

DOCTORS have found a new pill to help you lose weight - purely by accident.

Researchers discovered that a pill used for depression had the unexpected side effect of making patients shed their flab.

There is even evidence it can help people stop smoking! Now the British company who developed the drug - Bupropion - is considering

By MARTIN HALLE
happened because there had been nothing published about this drug having the ability to help weight loss," he says.

"The patients were pleasantly surprised because they had not been expecting such an effect. They had been given the drug because they were down about their weight."

Dr Gadde persuaded Bupropion's British manufacturers, Glaxo-Wellcome, to support a trial. He says: "I wanted to see if the drug would work under

Dr Gadde says: "A lot of the patients have said that while on the drug they can eat a fattening food like a small piece of pie and feel satisfied though not necessarily full."

Bupropion works in a different way to other anti-depressants. It acts on two brain chemicals, norepinephrine and dopamine, which are both implicated in the brain's reward and pleasure pathways.

Dr Gadde adds: "This probably explains why patients say the drug helps them feel more satisfied while not suppressing

