The Independent Sunday 15 June 2014

The Independent

Leading doctors warn guidance on statins could do more harm than good

Highly critical letter accuses NICE of seeking to 'medicalise five million healthy individuals'

CHARLIE COOPER

HEALTH REPORTER

TUESDAY 10 JUNE 2014

Plans to prescribe statins to millions more people must be put on hold, a group of leading doctors have said, in a highly critical letter which accuses the Government's respected health standards body of "conflicts of interest".

The letter, signed by nine doctors and academics including the president of the Royal College of Physicians (RCP), warns "public and professional faith" in the National Institute for Health and Care Excellence (NICE) could be lost and harm could be done to "many patients over many years".

It accuses the standards body of seeking to "medicalise five million healthy individuals".

The criticisms come after NICE issued draft guidance earlier this year recommending that cholesterol-lowering statins should be prescribed to all patients with at least a 10 per cent risk of heart attack or stroke in the next 10 years.

In their letter, the doctors said they were "seriously concerned that eight members of NICE's panel of 12 experts for its latest guidance have direct financial ties to the pharmaceutical companies that manufacture statins". They also warn that "overdependence on industry data raises concerns about possible biases".

Statins – taken by seven million people in the UK – are recommended for patients with a 20 per cent risk of cardiovascular disease in the next 10 years. While their benefits at cutting heart attack and stroke risk are not disputed, it has been claimed that industry-led studies had under-estimated the extent of statins' side effects. Some doctors fear in otherwise healthy individuals, the drugs may do more harm than good.

The doctors want the new guidance withdrawn until all data from statins' trials is made available to "credible researchers". In response to the criticisms, NICE said there was "no credible argument against [statins'] safety and clinical effectiveness" for patients with a 10 per cent risk.

Professor Mark Baker, director of NICE's centre for clinical practice, added: "Our approach is transparent, rigorous and sensible… Concerns about hidden data and bias the pharmaceutical

industry may or may not have are important issues and need to be resolved. NICE is part of the effort to do that but… we need to act in the best interests of patients on the basis of what we know now."

Statins Q&A

What are the concerns around statins?

There are no major concerns about statins themselves – it is more a question of who should be taking them. New draft guidance from NICE proposes to significantly lower the 'treatment threshold' so that millions more people at a lower risk of heart attack or stroke would be given them.

Why would that be a problem?

Many experts say it wouldn't, and would save lives. But others say that NICE is recommending statins for patients who have such low risk, that it would be unnecessary and expensive to give them statins, and the only beneficiaries would be the pharmaceutical companies that make the drugs.

What about the side effects?

Like all drugs statins have some side effects, but in high risk patients these are negligible compared to their benefits in cutting the chances of heart disease. But some studies have shown higher rates of the side effects – including muscle pain and increased likelihood of diabetes – and many doctors argue these could outweigh the small benefits that taking a statin would achieve for low risk patients.

Why is there no scientific consensus based on the evidence?

Some of the key findings on statins effectiveness and side effects comes from industry-funded studies. There is also a great deal of data which has not been made available for all researchers to see. Many doctors have argued that NICE should not make recommendations until all the data on statins is made available to all researchers.

Should I carry on taking my statins?

Absolutely, yes. The current guidance, under which you will have been prescribed a statin, is not disputed.

The Telegraph Sunday 15 June 2014

New NHS statins guidance 'risks harming patients'

Telling millions of healthy people to take statins risks harming 'many patients over many years', doctors warn Jeremy Hunt, the Health Secretary, and watchdogs

Proposals to advise twelve million people to take statins could have “worrying” consequences because the plans were borne out of an “overdependence” on studies funded by the pharmaceutical industry, doctors said Photo: Alamy

By Edward Malnick

10:00PM BST 10 Jun 2014

Millions of people over the age of 50 risk harming their health if they follow new NHS guidance telling them to take statins, leading doctors have warned the Health Secretary. Proposals to advise 12 million people to take the drugs could have “worrying” consequences because the plans were borne out of an “overdependence” on studies funded by the pharmaceutical industry, they say.

The group cites research, independent of the drug industry, showing that statins have been associated with a 48 per cent increase in the risk of diabetes in middle-aged women. Other potential side effects could include depression, fatigue and erectile dysfunction, they warn.

In a letter to Jeremy Hunt, the prominent clinicians, including the head of the Royal College of Physicians and a former chairman of the Royal College of General Practitioners, say that the majority of the National Institute for Health and Care Excellence (Nice) panel responsible for drawing up the guidelines has “direct financial ties” to firms that manufacture statins.

They say that those with “industry conflicts” should be barred from helping to prepare drug guidelines.

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Nice will publish its final recommendations next month, after a public consultation. In February it announced its plans to cut the “risk threshold” for statins in half — meaning that the vast majority of men aged over 50 and most women over the age of 60 are likely to be advised to take the drugs to guard against strokes and heart disease.

Experts said the changes would mean that the number of patients advised to take cholesterol-lowering drugs was likely to rise from seven million to 12 million, leaving one in four adults on the medication.

Nice says the guidance will prevent many people from becoming ill and dying prematurely. By contrast, recent academic papers have questioned the widespread use of statins, claiming that they cause harmful side effects and do not cut death rates — although the authors of two such articles in the British Medical Journal have since withdrawn statements after some figures they cited were found to be incorrect.

In their letter to Mr Hunt and Nice, nine doctors and academics warn that the guidelines will result in the “medicalisation of five million healthy individuals”.

They call on Nice to shelve the proposals until independent experts have been allowed to examine the data on which they have been based.

“The potential consequences of not doing so are worrying: harm to many patients over many years, and the loss of public and professional faith in Nice as an independent assessor,” they write.

“Public interests need always to be put before other interests, particularly pharma.”

The doctors and academics highlight a series of concerns that they say should result in publication of the guidance being delayed.

Led by Sir Richard Thompson, the president of the Royal College of Physicians, they accuse Nice of relying on “hidden data” to reach its conclusions, arguing that crucial studies have not been open to scrutiny. Almost all the research was funded by pharmaceutical firms and should be “open to analysis by a third party with appropriate expertise”, they write.

The doctors, who also include Prof Clare Gerada, a former chairman of the Royal College of General Practitioners, and Prof David Haslam, the chairman of the National Obesity Forum, added that they were “seriously concerned” that eight members of the Guideline Development Group had “direct financial ties to the pharmaceutical companies that manufacture statins”.

The eight members highlighted by the signatories included Dr Anthony Wierzbicki, the chairman of the panel, who declared involvement in a number of commercial clinical trials of new cholesterol-lowering drugs.

The doctors also drew attention to Emma McGowan, a specialist heart nurse who held a post sponsored by AstraZeneca for a year and has been paid by Amgen, another firm, to work on studies.

Dr Dermot Neely, the head of the clinical biochemistry department at Newcastle University and another member of the panel, has received funding from Roche Pharma, Genzyme, Aegerion, Amgen and Sanofi for taking part in “one-off advisory boards”.

All of the links to pharmaceutical firms were declared to Nice at the time that the panel was preparing guidance. The watchdog said in each case the involvement was “judged not to be specific enough to warrant withdrawal”.

A spokesman for Nice said: “The conflicts of interest declared by committee members involved in producing this guideline have been managed appropriately. They have not influenced in any way the draft recommendations on the use of statins.”

Responding to the letter, Prof Mark Baker, the director of the centre for clinical practice at Nice, said: “The independent committee of experts found that if a patient and their doctor measure the risk and decide statins are the right choice, the evidence clearly shows there is no credible argument against their safety and clinical effectiveness.”

SUNDAY EXPRESS

Doctors' ban on statins: Medics at war over drug advice

DOCTORS are in open revolt over plans to issue statins to millions of healthy people.

By: Giles Sheldrick

Published: Wed, June 11, 2014

They are opposed to instructions to force them to prescribe the pills, which they claim can cause a catalogue of crippling side-effects.

Today, in an open letter to the Health Secretary, nine leading medics say it is a step too far.

They want the National Institute for Health and Care Excellence, which issues guidance on what drugs doctors should prescribe, to refrain from final recommendations until “hidden” data on the adverse effects is released.

New guidance could see virtually all men aged over 55 and women over 65 encouraged to take the cholesterol-busting tablets to stave off fatal cardiovascular disease.

Their rebellion comes after the British Medical Association’s general practitioners’ committee voted unanimously to reject the guidance until “complete public disclosure of all clinical trials data”.

There are too many creeping adverse effects that can cause debilitation for years before they are picked up
Dr Ian Campbell

It urged doctors to ignore draft guidance which claims the simple-to-use drugs are safe for those with no history of heart conditions.

Cholesterol specialist Dr Malcolm Kendrick said: “Statins have a lot more side-effects than opinion leaders state. To say they have no side-effects is complete and utter nonsense.”

The Nice guidelines, he added, were like a decree from North Korean despot Kim Jong-un. “You just don’t go against them.”

The draft recommends offering statins to five million people with a 10 per cent or greater risk of developing cardiovascular disease within a decade. It will cost the NHS billions of pounds.

Last night family doctor Ian Campbell said: “There are too many creeping adverse effects that can cause debilitation for years before they are picked up – like muscle cramps and weakness.”

Most doctors say the most-effective way to prevent the onset of heart disease is to avoid being overweight, quit smoking and take regular exercise.

The open letter has been sent to Nice chairman Professor David Haslam as well as Health Secretary Jeremy Hunt. The nine signatories include Sir Richard Thompson, president of the Royal College of Physicians.

They call on Nice to refrain from any final recommendations until “hidden” data on “adverse effects” is released.

Professor Mark Baker, of Nice, said: “We have consulted on these proposals and the results of this consultation are currently being reviewed prior to our final recommendations next month.”

The draft encourages GPs to explore, with patients, ways of reducing risk – including lifestyle changes, he added. “It will help prevent many from becoming ill and dying prematurely.”

Eight million Britons now take statins.

Daily Mail

Mail Online

Sunday, Jun 15th 2014 12PM

Giving statins to millions more 'could be a disaster': Leading doctors say decision to give drugs to healthy Britons could cause harm to patients

- **NHS proposals to put more patients on statins 'potential disaster'**
- **Leading doctors claim panel of experts are linked to drugs firms**
- **Seven million patients in Britain take statins to control cholesterol**

By SOPHIE BORLAND

PUBLISHED: 00:46 GMT, 11 June 2014 | **UPDATED:** 06:44 GMT, 11 June 2014

Millions of healthy Britons are about to be given statins needlessly and exposed to debilitating side effects which include muscle pain and diabetes, leading doctors warn.

They say NHS proposals to radically increase the uptake of the drugs are a ‘public health disaster’ that will cause harm to many patients.

The group – which includes cardiologists, and senior GPs – is urging the government and the NHS drugs watchdog NICE to halt the plans. They also claim that eight of the 12-strong panel of experts who are drawing up the guidelines have financial links to drugs firms making statins – which stand to make a profit.

'Disaster': Millions of healthy Britons are about to be given statins needlessly which could lead to a 'public health disaster' if the NHS does not halt the plans, leading doctors warn

About seven million patients in Britain take statins to lower the cholesterol in their blood to prevent heart attacks and strokes. They are predominantly given to over-65s who have been diagnosed with heart disease or have a high risk of developing it based on their family history or lifestyle.

But in February, NICE – National Institute for Health and Care Excellence – published draft guidance advising GPs to prescribe statins to anyone with a 10 per cent risk of suffering a heart attack or stroke within the next decade. It claims this could save many lives at a minimum cost to the NHS as the drugs cost as little as 10p each.

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Experts say this would lead to the drugs being given to between five and ten million additional patients.

NICE will publish its final guidelines next month.

But the group of doctors say there is no evidence that giving statins to healthy people increases their life expectancy.

The group wrote to Health Secretary Jeremy Hunt to warn of the consequences of increasing statin prescriptions

On the contrary, they point to evidence showing they increased the risk of diabetes in middle-aged women by 48 per cent and cause fatigue and muscle pain.

The group also accuse NICE of looking only at evidence about benefits and possible side effects of statins that have been provided by drugs firms, which could be biased.

The leading doctors also argue that rather than prescribing statins, the NHS should be encouraging patients to lose weight and take more exercise.

In a letter to Health Secretary Jeremy Hunt and NICE, they wrote: ‘The consequences of not withdrawing this guidance are worrying: harm to many patients over many years, and the loss of public and professional faith in NICE as an independent assessor.

‘Public interests need always to be put before other interests, particularly pharma [the drugs industry].’

Professor Simon Capewell, professor of clinical epidemiology at the University of Liverpool, one of the doctors against the move, said: 'The statin recommendations are deeply worrying, condemning all middle-aged adults to lifelong medications of questionable value.'

Dr Malcolm Kendrick, a GP and member of the BMA General Practitioners sub-committee, who is also a member of the group said: 'Who knew that millions of people in the UK now suffer from statin deficiency syndrome? Mass statination is a triumph of statistics over common sense.

'Treating millions at a cost of billions based on data we are not allowed to see is an example of the corporatisation of medicine and will result in a public health disaster.'

And Dr David Newman, director of clinical research at Mount Sinai School of Medicine in New York, said: 'For most people at low risk of cardiovascular disease, a statin will give them diabetes as often as it will prevent a non-fatal heart attack.'

In response, Professor Mark Baker, director of the Centre for Clinical Practice at NICE, said: 'Cardiovascular disease maims and kills people through coronary heart disease, peripheral arterial disease and stroke. Together, these kill one in three of us. Our proposals are intended to prevent many lives being destroyed.'

NICE'S EXPERTS LINKS TO DRUGS COMPANIES

Concerns have been raised that eight of the 12-strong panel recommending widespread use of statins have financial links to the pharmaceutical companies that manufacture them.

They include Dr Anthony Wierzbicki, chairman of the NICE panel and a heart disease specialist at Guys and St Thomas' Hospital in London, who has ties to six firms, including Pfizer, Sanofi and Aventis, which sponsored his research into cholesterol-lowering drugs.

Dr Michael Khan, a heart specialist at University Hospitals of Coventry and Warwickshire, has been paid by drug companies investing in heart drugs to give lectures and sit on advisory boards. They include Amgen, a US firm which makes statins that has sponsored him to run a clinical trial.

Emma McGowan, a specialist heart nurse who also works at University Hospitals Coventry and Warwickshire, was sponsored by statin manufacturers AstraZeneca for the first year of her job. She was also paid by the same firm to attend conferences.

Dr Robert Dermot Neely, heart specialist at the University of Newcastle, has been paid by statin makers Roche, Genzyme and Aegerion to sit on advisory boards.

The experts declared these conflicts of interest to NICE. The Mail contacted them for comment but did not receive a reply.

Read more: http://www.dailymail.co.uk/health/article-2654651/Giving-statins-millions-disaster-Leading-doctors-say-decision-drugs-healthy-Britons-cause-harm-patients.html#ixzz34fyz7vs3

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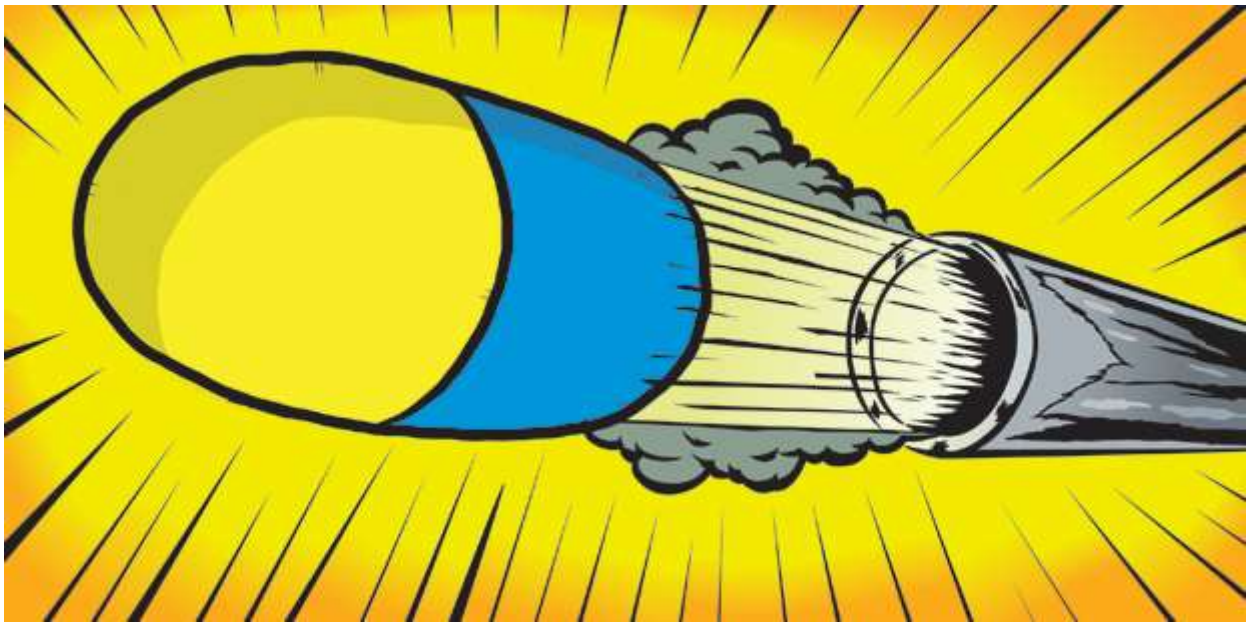
THE SPECTATOR

The truth about statins

Cholesterol-lowering statins don't help most of the people who take them, says Dr James Le Fanu and — despite recent reports — the side effects can be dire

COVER FEATURE 11 CommentsDr James Le Fanu 31 May 2014



Forty years ago Henry Gadsden, chief executive of the drug company Merck, expressed his frustration that the potential market for his company's products should be limited to those with treatable illness. Ideally, he said, he would like 'to sell to everyone'. 'Henry Gadsden's dream has long since come true,' observes the medical commentator Ray Moynihan. 'The marketing strategy of drug companies now targets the hundreds of millions of the apparently well, persuading them they have some medical condition that warrants treatment.'

The jewel in the crown of modern pharmaceuticals and the apotheosis of Henry Gadsden's vision of selling 'to everyone' are cholesterol-lowering statins. They are the wonder drugs of our age, credited with saving tens of thousands of lives and generating for their manufacturers £15 billion a year in annual revenues. They are, by far, the single most profitable drug ever discovered. Already the most widely

prescribed class of drugs in Britain, they could soon become even more so following the recent recommendation by a committee of cholesterol experts advising the National Institute for Health and Clinical Excellence (Nice) that those eligible for statins should be extended to everyone aged 60 and over, boosting the numbers taking them to an eye-watering 12 million — or one in four of the adult population.

Intuitively, this seems a bad idea for any number of commonsensical reasons but, claims Sir Rory Collins, Professor of Medicine and Epidemiology at the University of Oxford, 'The evidence supports these recommendations — the drugs are effective.' He concedes that some 'may not like the idea of mass medication' but they can be reassured at least that statins have been found to have 'virtually no side effects'. Dr Judith Finegold of the National Heart and Lung Institute, in a recent, much-publicised study scrutinising nearly 80,000 patients, found the incidence of symptoms commonly attributed to statins to be no different from those of volunteers taking a placebo.

Both Sir Rory Collins's endorsement of the benefits of statins and Dr Finegold's reassurances about the low incidence of side effects are based on the findings of drug company-sponsored clinical trials — not perhaps the most reliable source of evidence, given their well-known reputation for consistently reporting 'favourable efficacy and safety results'.

Professor John Abramson of Harvard Medical School has a rather different take, drawing attention in a critical review in the *British Medical Journal* last year to the main difficulties in assessing the findings of these clinical trials. First, the claim that statins are 'effective' conceals the minuscule benefit they confer on the vast majority for whom they have 'no significant effect on overall mortality' (in other words, they do nothing to prolong life in the majority of people taking them). Statins reduce the absolute risk of heart attack and stroke in just 2 per cent of cases. The outcome in those at 'high risk' (with markedly elevated cholesterol levels or a previous history of circulatory disorders) is only marginally better — preventing a further episode in just 4 per cent, with a 1 per cent reduction in 'overall mortality'.
Thus the promotion of 'statins all round' — given these modest benefits — could really be justified only if indeed they have 'virtually no side effects'. This is hotly disputed. Statins were in the press earlier this month after the British Medical Journal accepted that it had published flawed research last autumn over-estimating

the side effects of statins. The research had claimed that 18 to 20 per cent of patients suffered debilitating side effects, and this statistic has now been withdrawn by the authors. But while their figure may have been an over-estimate, that doesn't necessarily mean statins have no side effects.

Indeed, this would be most unlikely — not least, as Professor Abramson observes, because it appears that some clinical trials may have excluded patients unable to tolerate the drugs. It is certainly contradicted by independent surveys of those taking statins that suggest the prevalence of muscular aches and pains to be 100 times greater than reported in trials, along with numerous other problems of fatigue, depression, poor memory and concentration, sleep disturbances and reduced libido.

I first became aware of the scale of this hidden epidemic of apparent statin-induced symptoms after describing in my *Telegraph* column the experience of a man in his seventies whose general health following the successful repair of an aortic aneurysm had gradually deteriorated to a state (as he described it) of 'chronic decrepitude' — such that when flying to Hawaii to attend his son's wedding he had required a wheelchair at the various stopovers. Yet returning three weeks later he had walked back through Heathrow — having forgotten to pack the statins he had been taking since his operation.
This account of his near-miraculous recovery following his statin-free excursion prompted hundreds of letters and emails from readers describing their own similar experiences. Those who had been previously fit and well were usually quick to spot the adverse effects on their wellbeing: 'Within a couple of weeks I went from an active 65-year-old to a doddering old man,' as one put it. Most only realised the devastating impact of statins on their lives when advised by friends and relatives to stop taking them.

Thus the 'bottom line', as Professor Abramson describes it, is that for more than 95 per cent of those taking statins, they neither prolong their lives nor prevent serious illness while some may experience side effects ranging from the 'minor and reversible to the serious and irreversible'.

Abramson's trenchant critique of this unprecedented experiment in mass medication — and its consequences — raises the question of how it has come about. Here two distinct, if interrelated, factors are highly relevant. The first is the progressive entanglement and blurring of the boundaries of interest between the pharmaceutical industry and the medical profession. Many of the 'key opinion leaders' (or KOLs as they are known to the industry), the senior physicians and experts involved in one way or another with evaluating and promoting the widespread use of statins, have ties with the drug companies that manufacture them and are rewarded for their efforts. Next, if more obscurely, the argument for widening the constituency of those taking statins is predicated on an influential, if speculative, theory much favoured by epidemiologists and public health experts known as 'the population approach'. This maintains that, rather than focusing efforts on those at 'high risk', the prevention of common illnesses – such as heart disease – is best achieved by lowering the average cholesterol level in everyone ('the population').

Within this context it is possible to trace the rise of statins over the past 30 years, starting with the presumed link established back in the 1980s of the causative role of cholesterol in circulatory disorders — the thesis that those indulging in (for example) bacon and eggs for breakfast raised the levels of cholesterol in the blood and this in turn clogs up the arteries, increasing the risk of a heart attack. The imagery is powerful, if simplistic. There is (perhaps surprisingly) no correlation in the pattern of heart disease over the past 60 years with trends in the consumption of 'high fat' foods such as meat and dairy products. Cholesterol cannot be entirely innocent, even if it plays a vital role in many bodily functions. Those with a genetic defect resulting in markedly elevated levels are undoubtedly at greater risk of heart disease.

The many attempts to encourage people to switch to a 'healthy' low fat diet were not successful, prompting a switch of emphasis in favour of cholesterol-lowering drugs. The results of the trial of the first statin, Lovastatin — developed by Henry Gadsden's company and launched in 1987 — were certainly encouraging in this regard. Soon enough several other drug companies, recognising its bounteous potential, came up with their own versions and in the subsequent scramble to secure a share of this lucrative market, the clinical trials assessing their efficacy were transformed into an ingenious and highly successful form of marketing.

Organised on a massive scale involving up to 10,000 patients, their favourable results — announced with great razzmatazz at major medical conferences — generated an almost evangelical zeal for the project of 'statins for all'.

Meanwhile, successive expert committees charged with establishing 'clinical practice guidelines' have invoked the principle of 'the lower the cholesterol the better' to reduce the cut-off point for initiating treatment to well below the 'normal' or mean cholesterol level — expanding by millions the number eligible for statin therapy. Doctors were still free to use their clinical judgement as to whether or not to adhere to these guidelines. But this changed in 2003 when the Department of Health, strongly influenced by the proponents of the 'population approach', linked general practitioners' remuneration to their success in achieving predetermined targets obliging them to assess the 'cardiovascular risk' in all their patients and prescribe medication to lower it. Circulatory disorders are strongly age-determined, so general practitioners can maximise their income by the simple expedient of routinely prescribing statins to the elderly — who are, of course, more vulnerable to their potential side effects.

By now it will be apparent that in one way or another a considerable proportion of the medical profession from the KOLs to humble general practitioners, epidemiologists and public health doctors are committed to supporting statins — and they have no avenue of retreat. They can scarcely concede it might not, after all, be a good idea to prescribe potent drugs to vast sections of the population. And it has recently emerged that statins, besides everything else, may also cause diabetes in almost 2 per cent of those taking them — a small percentage, one might think, until one does the sums and realises this adds up to more than 5,000 new cases a year, and 27,000 over a five-year period. And diabetes, as we all know, is a serious condition, not least in predisposing people to those circulatory disorders the statins are intended to prevent — along with impaired vision, neuropathy and impotence.

The drug companies have obviously played a central role in orchestrating the rise of statins. That is only to be expected and indeed one can almost imagine the shrewd Henry Gadsden admiring the elegance of the strategy with which his successors have realised his vision — recruiting those KOLs to the cause and exploiting to their considerable advantage the epidemiologists' 'population approach' and government policy on the remuneration of family doctors. Many might rightly be concerned at

the unflattering insight into the current intellectual state of medicine where doctors should so uncritically endorse the findings of industry-funded clinical trials.

But there is more than this. Biology is complex and the biology of cholesterol very complex, since cholesterol is the foundation for several important hormones and integral to the structure of cell membranes. There is little doubt that it plays a role as a contributory — if not determinant — factor to circulatory disorders, but it is folly to suppose it might be possible to reduce its concentration in the body without running into unexpected problems.

I am haunted by an image drawn from the many experiences of readers related to me over the last few years. It is of a woman in her mid-seventies whose physical aches and pains, progressive immobility and deteriorating memory are, her family doctor has advised her, only to be expected at her age. That evening before retiring to bed she takes a daily dose of the most commonly prescribed drug in Britain.

James Le Fanu is a GP, author and Daily Telegraph columnist.

This article first appeared in the print edition of The Spectator magazine, dated 31 May 2014

BBC NEWS

10 June 2014 Last updated at 23:33

Scrap plan to extend statin use, say doctors

By Nick Triggle Health correspondent, BBC News

Continue reading the main story

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Proposals to extend the use of statin drugs should be scrapped, a group of leading doctors and academics says.

The National Institute for Health and Care Excellence published draft guidance in February calling for their use to be extended to save more lives.

It could mean another five million people in England and Wales using them on top of seven million who already do.

But in a letter to NICE and ministers, the experts expressed concern about the medicalisation of healthy people.

The letter said the draft advice was overly reliant on industry-sponsored trials, which "grossly underestimate adverse effects".

And it added: "The benefits in a low-risk population do not justify putting approximately five million more people on drugs that will then have to be taken lifelong."

The drugs reduce levels of cholesterol in the blood, lowering the risk of a heart attack or stroke.

The signatories include Royal College of Physicians president Sir Richard Thompson and former Royal College of GPs chairwoman Clare Gerada as well as cardiologists and leading academics.

Side-effects

Prof Simon Capewell, an expert in clinical epidemiology at Liverpool University and one of the signatories, said: "The recent statin recommendations are deeply worrying, effectively condemning all middle-aged adults to lifelong medications of questionable value.

"They steal huge funds from a cash-strapped NHS and they steal attention from the major responsibilities that government and food industry have to promote healthier life choices for ourselves and our children."

Currently, doctors are meant to offer statin tablets to the estimated seven million people who have a 20% chance of developing cardiovascular disease over 10 years, based on risk factors such as their age, sex, whether they smoke and what they weigh.

Statins and risk

• Statins are a group of medicines that can help lower rates of so-called "bad cholesterol" in the blood

• They do this by curbing the production of low-density lipoprotein cholesterol in the liver

• High rates of LDL are potentially dangerous as they can lead to hardening and narrowing of the arteries, known as atherosclerosis, which increases the risks of strokes and heart attacks

• Doctors use a risk calculator called QRisk2 to work out a person's chance of having a stroke or heart attack to decide if they should be given statins

• The calculation factors include age, weight and smoking

• If someone has a 10-year QRisk2 score of 20%, then in a crowd of 100 people like them, on average, 20 people would get cardiovascular disease over the next 10 years

But the draft guidance suggested that people with as low as a 10% risk should be offered the treatment.

Cardiovascular disease develops when fatty substances build up in the arteries and narrow them, which can lead to heart attacks and stroke.

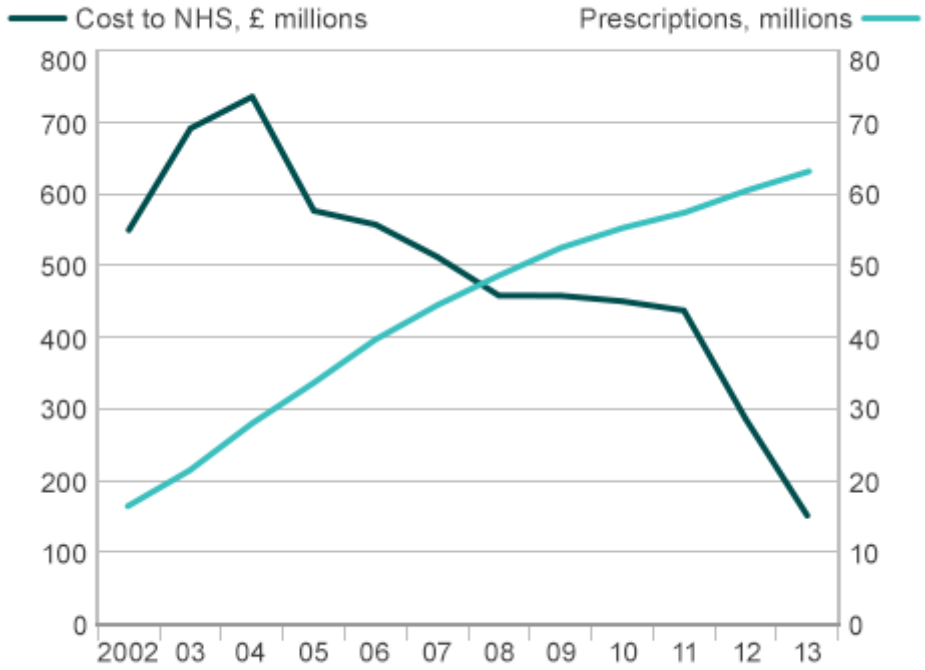
Too much cholesterol in the blood can lead to these fatty deposits. Statin drugs work by lowering cholesterol.

Eating a healthy diet, doing regular exercise and keeping slim will also help lower cholesterol.

Like all medicines, statins have potential side-effects. They have been linked to muscle, liver and kidney problems, but just how common these are is a contentious issue.

One of the signatories to the letter is London cardiologist Dr Aseem Malhotra, who last month had to **withdraw claims** he made in a British Medical Journal article that a fifth of people who use statins experience side-effects.

Statin use and cost in England, 2002-2013



Source: Prescription Cost Analysis and HSCIC

'Extremely painful'

"I was prescribed Simvastatin about nine years ago following heart problems," says John Cakebread, from Kent.

"I stopped taking the medication six years later after researching the subject on the internet and finding out about side effects.

"I have now been left with peripheral neuropathy in the feet.

"This is extremely painful.

"My GP refuses to acknowledge this condition and that it could be caused by statins.

"He still wants me to take this medication, but I have refused."

Mike Knapton, of the British Heart Foundation, said NICE was right to want to extend the use of statins.

"Evidence shows that statins are a safe, effective, cholesterol-lowering drug and proven to lower the risk of heart disease."

He added that, if anything, NICE should go further by looking at the lifetime risk rather than 10-year timeframe being proposed.

NICE has consulted on its draft proposals and is expected to publish final guidance at the end of July.

Prof Mark Baker, from NICE, said as well as the consultation the recommendations are being peer-reviewed.

He also pointed out that the guidance did not say patients had to go on these drugs - as GPs and patients can also discuss lifestyle changes to reduce risk - but just gave them the option of using them.

"This guidance does not medicalise millions of healthy people. On the contrary, it will help prevent many from becoming ill and dying prematurely," he added.

theguardian

Diets make us fat. The solution is simple

To tackle obesity we should advise people to eat real food, provided by the planet, not fake food, provided by manufacturers

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- **Zoe Harcombe**

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'We should return to the meat, fish, eggs, milk, butter, vegetables and grains in granny's larder and shun the concoctions adorning the shelves today.' Photograph: Niall McDiarmid/Alamy

"British girls have become the fattest in Europe" was this week's brutal headline. According to a global review published in the Lancet, 29.2% of UK females under 20 are overweight or obese. Males under 20 weighed in at 26.1% – not much better, but nine European countries were even worse, so our boys escaped the attention.
The most striking aspect of the research for me was that no country has recorded a significant fall in obesity levels since 1980. Why have we all been getting fatter since then?

To understand the obesity epidemic we need to know when it started. In 1972, 2.7% of men and women in the UK were obese and we barely needed to record obesity in children. By the start of the new millennium, 22.6% of men and 25.8% of women in the UK were obese. What went wrong?

The short answer is: we changed our dietary advice. More accurately, we did a U-turn in our dietary advice from "farinaceous and vegetable foods are fattening, and saccharine matters are especially so" to "base your meals on starchy foods".

The ideal for healthy eating in the UK is called the eatwell plate. Or as I refer to it, the eat badly plate. You may have seen it on the walls of schools and surgeries, but have you actually looked at it? Chocolate, sweets, biscuits, cake, cereal, baked beans, flavoured yoghurts and even a can of cola. And we wonder why we have an epidemic of type 2 diabetes.
Telling everyone to eat "plenty of potatoes, bread, rice, pasta and other starchy foods" is why we have an obesity epidemic. But why does it affect girls especially?

Just as our dietary advice is wrong, so is our weight loss advice. We have known for almost a century that calorie deficits lead to short-term weight loss, followed by rapid regain – invariably beyond the starting weight. Ancel Keys confirmed this in the 1940s and Marion Franz ended the debate in 2007 with a review of 80 weight loss studies, showing the familiar loss, regain and then some.
This will be very familiar to anyone who has tried to eat less. You probably weren't that overweight when you started the first calorie-controlled diet. You lost weight; gained it back and a bit more; tried again; lost a bit less; gained a bit more. That's what UK adults, women especially, have been doing for the past 30 years and our daughters have copied us.

In 2009 Fearne Cotton made an insightful documentary, The Truth About Online Anorexia, in which she visited a school in west London and talked to a class of 10-year-olds about body image and calories. "I don't like my body," said one girl, "I think I weigh too much."

When asked about calories she knew the content of a small Kit Kat and said "calories are bad 'cos you have to try and spend all your time exercising trying to burn them off".
In the UK females are starting to eat less from a younger age and, ironically, that's why they'll end up weighing more from a younger age. Because diets – and the eating disorders that so often follow them – make us fat. Dutch researchers presented recent findings at the European Conference on Obesity this month. Muscle loss on low-calorie diets is substantial, not easily recoverable and contributes to impaired metabolism, hunger and weight gain.
New obesity guidelines published this week by the National Institute for Health and Care Excellence (Nice) acknowledge the failure rate of dieting with targets lowered to a remarkably unambitious goal of achieving and sustaining a 3% loss. Despite this, the advice that is clearly not working has not been updated.
We need to teach young people the difference between real food, provided by the planet, and fake food, provided by manufacturers. We have to ditch every public health document, diagram and web page and replace it with three words: eat real food. We should return to eating the meat, fish, eggs, milk, butter, vegetables and grains in granny's larder and shun the concoctions adorning the shelves today. We need children to know the nutritional content of food, so that they are aware steak is good but confectionery is bad. They should be eating for health and energy; not to fear the calories that they need to thrive.

As in so many areas, we have failed young people. We can't turn the clock back on resource utilisation or financial burden, but we can go back to the diet of our childhoods. And we must.