

**Press Release: Embargoed 23:30 hrs (GMT- UK) Tuesday 10<sup>th</sup> June, 2014**

## **Leading Doctors Reject Latest Statin Guidance From The National Institute for Health and Care Excellence**

An open letter has been sent to the chair of NICE and the secretary of state for health, Jeremy Hunt, from leading doctors in primary care, secondary care and academia. They reject the recent draft guidance from NICE to reduce the threshold for prescribing statins to those with a 10% risk of cardiovascular disease (potentially treating an additional five million healthy individuals).

The letter is signed by a number of leading figures in health including the president of the Royal College of Physicians, Sir Richard Thompson, Professor Clare Gerada, Past Chair of the Royal College of General Practitioners and Professor Simon Capewell, Clinical Epidemiologist at the University of Liverpool.

Other signatories include Professor David Haslam, Chair Of The National Obesity Forum, GP Dr Malcolm Kendrick, London Cardiologist Dr Aseem Malhotra and Professor David Newman, Emergency Medicine physician and Director of clinical research and Mount Sinai School of Medicine, New York.

They address six major concerns and call on NICE to refrain from any final recommendations on reducing the threshold for statin guidance until these are fully addressed.

These six key areas are:

1. The medicalization of millions of healthy individuals
2. Conflicting levels of adverse events
3. Hidden data
4. Industry bias
5. Loss of professional confidence
6. Conflicts of interest

The group state the benefits of statins in a low risk population do not justify putting millions of extra people on a drug which then has to be taken lifelong.

They also express serious concerns that the data driving the latest guidance comes almost entirely from pharmaceutical sponsored studies. Because extensive research reveals that industry sponsored trials systematically produce more favourable outcomes than non-industry sponsored ones. Industry trials also grossly underestimate adverse effects, partly by removing patients who fail to tolerate the drug in the selection process. They state "relying on these studies alone will not represent those patients taking the drug in the real world."

The group cite important findings from non-industry sponsored studies which include a 48% increased risk of developing diabetes in middle aged women taking statins, while a robust randomised controlled trial revealed that 40% of women had reduced energy and fatigue. Others experienced psychiatric symptoms or erectile dysfunction.

They call on the Cholesterol Treatment Trialists Collaboration who have commercial agreements with the pharmaceutical industry to release all data on statins which is currently being concealed for review by independent researchers to help explain major discrepancies in several industry sponsored studies of statin adverse effects.

The leading doctors also mention that GPs feel that greater prescribing of statins to healthy people is a "step too far" citing the General Practitioners committee's rejection of NICE guidance a few weeks ago until it is supported by evidence derived from complete public disclosure of all clinical trials data"

The group express "serious concerns" that 8 of 12 of NICE's panel of experts on latest statin guidance have direct financial ties to the companies that manufacture statins. They instead emphasise that parties with industry conflicts should not be participants in generating recommendations on drug use across the population.

The leading doctors call on NICE “ to withdraw the current guidance on statins for people at low risk of cardiovascular disease until all the data are made available.”

They conclude: “The potential 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.”

Professor Simon Capewell, Professor of Clinical Epidemiology at the University of Liverpool said,  
“Two decades of research has confirmed the obvious: doctors receiving drug industry funding produce recommendations favouring the industry. It also represents a further embarrassment for NICE. NICE urgently need to develop a better mechanism for controlling these conflicts of interests. 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”

London Cardiologist Dr Aseem Malhotra said,

“Although there is good evidence that the benefits of statins outweigh the potential harms in those with established heart disease, this is clearly not the case for healthy people. For example a doctor wouldn’t give chemotherapy to a patient who didn’t have cancer or prescribe insulin to someone without diabetes. When you add up doctors’ appointments, unnecessary suffering for those who experience side effects that interfere with the quality of life, the illusion of protection of taking a drug that won’t reduce the risk of death in healthy people- and the increasing burden of chronic disease which is predominantly lifestyle related- prescribing statins to millions of healthy people would increase costs to the NHS, not reduce it.”

Dr Malcolm Kendrick, GP and member of the British Medical Association’s General Practitioner’s sub-committee said,

“Who knew that millions of people in the UK now suffer from statin deficiency syndrome? Mass statination is the triumph of statistics over common sense. Treating millions at a cost of billions, all based on data we are not allowed to see is another example of the corporatisation of medicine and will result in a public health disaster.”

Dr David Newman, Assistant Professor of Emergency Medicine and Director of clinical research at Mount Sinai School of medicine , New York said,

“I am always embarrassed when I have to tell patients that our treatment guidelines were written by a panel filled with people who stood to gain financially from their decisions. The UK certainly appears to be no different to that of the United States. The truth is 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—and they won't live any longer taking the pill. That’s not what patients are looking for.”

The full list of signatories:

Sir Richard Thompson, President of the Royal College of Physicians

Professor Clare Gerada, Past Chair of the Royal College of General Practitioners and Chair of NHS Clinical Transformation Board

Professor David Haslam, General Practitioner and Chair of the National Obesity Forum

Dr J S Bamrah, Consultant Psychiatrist and Medical Director of Manchester Mental Health and Social Care Trust

Dr Malcolm Kendrick, General Practitioner and Member of the British Medical Association's General Practitioners sub- Committee

Dr Aseem Malhotra, London Cardiologist.

Dr Simon Poole, General Practitioner

David Newman, Assistant Professor of Emergency Medicine and Director of Clinical Research, Mount Sinai School of Medicine, New York

Professor Simon Capewell, Professor of Clinical Epidemiology, University of Liverpool

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