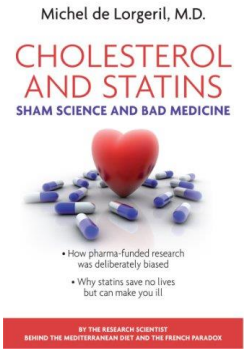

Ă**Cholesterol and Statins; Sham Science and Poor Medicine**ñwas initially published in French in 2008, under the title "**Cholestérol, mensonges et propagande**". Since then, crucial scientific, medical and sociological data have come to light and our interpretation of the facts, fed and consolidated by numerous testimonials, has evolved. Much has happened in the past five years and, although some elements were already mentioned in our book "**Preventing Strokes and Myocardial Infarction**" (2011), we took the opportunity of this English edition to review and update them.

Whatôs new since 2008? Three striking points come to mind. First, the emergence of serious undesirable side effects to statin therapy which had,until then, remained concealed or denied by many scientists, doctors and patients. The now well-established connection between statins and new-onset diabetes is probably the most tragic impact, not to mention the cancer risks inherent to diabetes and other mechanisms, notably the interference of statins with omega-6 and omega-3 FA metabolic pathways.The latter seems particularly involved in breast cancer processes. Consequently, the section devoted to the toxic effects of statins has been considerably expanded in this first English edition.

The completion of the CrestorÊ (or rosuvastatin) file was another striking event. Why did it matter? Because CrestorÊ , last in line, was the only statin to be assessed and sold *after* the disgraceful Vioxx Ê affair (IV), which eventually led to the nearly worldwide implementation of the 2006ï 2007 New clinical trial regulations. By imposing heavier sentences and fines in case of malpractice, these new regulations brought about major changes in the way clinical trials were conducted. More importantly, they imposed optimal transparency, notably concerning the reporting process. From then on, on application, all clinical trials were compelled to state the dates of beginning and completion. Once approval had been granted by the competent health authority, trial results had to be made public according to a predetermined schedule. This was far from perfect as it did not provide for access to the raw trial data. Nevertheless, it was still a great improvement. Under these new regulations, industrialists ï and any academic investigator or expert working for them ï became increasingly cautious, mainly for fear of being taken to court. Scientific and medical reports and publications thus became easier to read, not to say easier to interpret, at least for those of us who wished to keep our eyes wide open. If we restrict ourselves solely to the problem of statins and cholesterol reduction, the main thing that occurred after the publication of the new regulations is that all subsequent trial results were either negative (no clinical benefit) or flawed by major biases, as seen in the JUPITER trial [AMB 2009]. This evaluation of the effects of rosuvastatin (CrestorÊ) gave rise to such an extraordinary saga that an entire chapter is now devoted to it (see chapter 18). The *New regulations* also dictated that the results of all trials were to be published, whether or not they supported the expected benefits of the study drug. This considerably changed the way in which the drug industry marketed new drugs, as illustrated by the ENHANCE trial which involved patients suffering from Familial Hypercholesterolemia (HF) and is detailed in Chapter 2.

The third striking event concerns the increasingly critical voice of public opinion and media: querying cholesterol-related dangers and the very need for cholesterol-reducing drugs have ceased to be taboo. Drug policies often make the headlines of the morning or evening papers and it is not unusual to see them qualified as lax, or even ludicrous. For readers who remain sceptical, I recommend two recently published articles. The first, *"Big Pharma. often commits corporate crime, and this must be stopped"* was published by Professor Peter C. Gøtzsche, of the Copenhaguen Rigshospitalet in Denmark, in the *British Medical Journal* [2012;345: e8462]. Not only did that article, and the one published by the BMJ in January 2013 (BMJ 2013;346: 21), quote the exact charges brought against several major pharmaceutical laboratories, it also found the new proposed EU clinical-trial regulations seriously wanting. It lists several measures that need to be taken, notably regarding fines and sanctions, patient safety, the way in which drugs are used and the conditions in which research is conducted. The second article, *"Why we can't trust clinical guidelines"* was written by Jeanne Lenzer, a New York medical investigative journalist and also published by the BMJ (2013;346: f3830). The significance of her accusations is frightening, implying that current medical practices ï supposedly based on scientific guidelines ï might not, primarily, be evidence based! All it takes to have some idea of this permanently feverish world is a good pair of ears, and/ or a visit to a few health-dedicated websites (notably American). In France, certain general media have already relayed my arguments, quite intelligently. Cholesterol-lowering drug victims have testified publicly on our blog [http:// michel.delorgeril.info], privately or on certain Internet forums; their accounts have enabled us never to stray too far from day-to-day clinical realities and to remain acutely aware of these personsôsuffering ï in short, to stay in touch with r*eal life*! Doctors and scientists have rallied to our position ï even if they did not always dare to voice their opinions too loudly for fear of reprisal from their colleagues, or from the health authorities. And we found their additional information particularly valuable. Our initial investigations were considerably enriched by all these new and original data which we have integrated into in this English edition of *"Cholesterol and Statins: Sham Science and Bad Medicine"* In short, our progress has been considerable and our knowledge much improved. We accept full responsibility for all these changes. In no way are we backing down! Our overall opinion remains unchanged:

"Cholesterol is not to blame and cholesterol-lowering drugs, dietary supplements (red-rice yeast included), margarines with added phytosterols and anti-cholesterol diets are all useless and hazardous ...
This leads us to our final conclusion, this time based on the comparison of statins vs. statins, that the older statins [Simvastatin/ZocorÊ , Pravastatin/ElisorÊ , Lovastatin/MevacorÊ ,] are not different from the most recent ones [Atorvastatin/TahorÊ /SortisÊ , Rosuvastatin/CrestorÊ] and that lowering cholesterol levels with a statin yields absolutely no detectable clinical benefit. This absence of any beneficial effect prohibits the prescription (and refund by healthcare insurances) of drugs which are both useless and toxic. Because, as I shall demonstrate in Part IV, statins are truly toxic ..." [1]

"In this year 2014, I am much perplexed when I observe that despite the scientific and medical data accumulated against the cholesterol theory and despite the succession of undeniable demonstrations of the ineffectiveness of statins and of their toxicity, no public debate has been initiated and there isnô even the beginnings of any virtuous exchanges among scientists. **How can this phenomenon be explained?** It is staggering to see that doctors (in charge of their patientsôhealth), scientists (who normally have the responsibility of looking for the truth) and administrators (in public health) are still unable to speak serenely of a problem which affects several hundred million citizens worldwide. **What are the true stakes involved in these issues? Why such brutal blockages?** The answer is simple: there is no debate because if one existed, it would imply looking for consensus when there is no possible compromise. Consensus is unachievable because warnings and red flags have been seen by all, public and media included. Claiming unawareness will become increasingly difficult as time goes by. In fact, we will be left with one of two alternatives: either ñI didnô see anything coming and do not deserve my positionòor, ñI knew, but didnô say anythingòand therefore ñI might be accused of failure to assist persons in dangerò To put it plainly, the only choices left are to appear as a total idiot or as a criminal! We all understand that everyone would rather, like the proverbial ostrich, hope that the storm will pass us by and spare our heads. **What solution will those elites find to pull back satisfactorily, without some ending up in prison and others being taken for fools?** These are indeed the only choices that will remain for those who chose to hang onto the statin raft until the last minute! We might have an idea of the future of statins by observing what is happening today with another health scandal, that of the French drug Mediator Ê . Both are not exactly comparable for two reasons: the first is that France was the only country guilty of not revealing the scandal; the second is that, unlike statins, the main feature of the Mediator scandal is the very absence of science! With statins, the scandal knows no border and science is overabundant rather than absent. The only problem is that with regard to statins, that science is dubious, not to say corrupted! So all sorts of unexpected developments, ñfizzling outsòand U-turns are likely to arise when the statin scandal explodes, which, judging by the Mediator affair, we cannot foresee. There is another major difference between Mediator and statins. The undesirable effects of statins, which are either denied by the experts claiming ñits rare, therefore insignificantò, or greatly underestimated, since the most dangerous and irreversible ones are particularly silent and devious. All have an impact on the risks of cancer, diabetes and neurological toxicity. So, contrary to Mediator, the statin issue is unlikely to be approached from the angle of its side effects or toxicityé unless some extremely meticulous investigators, national health insurance statisticians for instance, decide to examine the connections between statin prescription and various diseases, notably cancer and diabetes. If the statin issue cannot be debated in court, as doctors and scientists are unable to debate among themselves, it will be up to the general public to change from the status of victim to that of champion, with citizens as witnesses, jury and judges! This is why I persist in informing the general public through my scientific publications, books and blog [http://michel.delorgeril.info] ..." [2]

Michel de Lorgeril, Mikael Rabaeus: "Beyond Confusion and Controversy, Can We Evaluate the Real Efficacy and Safety of Cholesterol-Lowering with Statins?" Journal of Controversies in Biomedical Research 2015; 1(1):67-92. www.jcbmr.com/index.php/jcbmr/article/viewFile/11/24

Dr. med. Michel de Lorgeril
(b.1950)
Französischer Arzt und Kardiologe, Forscher am CNRS in Grenoble (I)
und international anerkannter Experte für Ernährungsfragen.
Aus seinem Buch: "Cholesterol and statins: Sham science and bad medicine" Kindle Edition Thierry Souccar Publishnig 2014
("Cholestérol, mensonges et propagande" 2008/2014) Translated from the French by Anne Pietrasik. [1] Foreword to the English edition: Kindle-Positionen 175-182, K-P 182-190, K-P 190-197, K-P 197-204, K-P 204-211, K-P 211-218, K-P 218-225; K-P 3078-3082
[2] Postscript: K-P 4088, K-P 4089-4093, K-P 4093-4099, K-P 4099-4105, K-P 4105-4110, K-P 4110-4115, K-P 4115-4117
Portrait - Aus: www.amazon.fr/Michel-de-Lorgeril/e/B004MT5YHY
Robert DuBroff (II), Michel de Lorgeril (III): "Cholesterol confusion and statin controversy" World J Cardiol. 2015 Jul 26; 7(7): 404ï 409
(I) Das "Centre national de la recherche scientifique" (= Nationales Zentrum für wissenschaftliche Forschung) ist als nationale französische Forschungsorganisation dem Forschungsministerium unterstellt und widmet sich der Grundlagenforschung. Es ist vergleichbar mit der deutschen Max-Planck-Gesellschaft, allerdings wesentlich größer und weniger eng fokussiert. Das CNRS bildet mit einem Etat von 3,4 Milliarden Euro und 32.000 Beschäftigten (2013) die zweitgrößte Forschungsorganisation in Europa nach der Helmholtz-Gemeinschaft Deutscher Forschungszentren." Aus: https://de.wikipedia.org/
(II) Department of Medicine, Division of Cardiology, University of New Mexico School of Medicine, Albuquerque, United States
(III) PRETA-TIMC-IMAG, Equipe Cî ur and Nutrition, CNRS UMR 5525-UJF-INP, Faculté de Médecine, Université de Grenoble, France
[AMB 2009] https://www.der-arzneimittelbrief.de/de/Artikel.aspx?SN=6931
(IV) Harlan M. Krumholz, Joseph S. Ross,2 Amos H. Presler, David S. Egilman: "What have we learnt from Vioxx?"
"Rofecoxib (Vioxx) was introduced by Merck in 1999 as an effective, safer alternative to non-steroidal anti-inflammatory drugs for the treatment of pain associated with osteoarthritis." BMJ. 2007 Jan 20; 334(7585): 120ï 123
In: www.draloisdengg.at