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How You've Been Misled About Statins

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STORY AT-A-GLANCE -

- More than 35 million Americans are on a statin drug, making it one of the most commonly prescribed medicines in the U.S. Lipitor — which is just one of several brand name statin drugs — is one of the most profitable drugs in the history of medicine
- The "statin empire" is built on prescribing these drugs to people who really don't need them and are likely to suffer side effects without getting any benefits
- By simply revising the definition of "high cholesterol," which was done in 2000 and again in 2004 in the U.S., millions of people became eligible for statin treatment, without any evidence whatsoever that it would actually benefit them
- In 2013, the American College of Cardiology and AHA revised their statin guideline to include a CVD risk calculation rather than a single cholesterol number. This resulted in another 12.8 million Americans being put on statin treatment even though they didn't have any real risk factors for CVD
- Industry-biased research, the hiding of raw study data, deceptive statistical tricks, silencing of dissenters, censoring of critics and the use of fear-based PR are other strategies employed to manipulate public opinion and doctors to keep prescribing statins to an ever-widening population base

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Statins are HMG-CoA reductase inhibitors; that is, they block the enzyme in your liver responsible for making cholesterol (HMG-CoA reductase). According to Drugs.com, more than 35 million Americans are on a statin drug, making it one of the most commonly prescribed medicines in the U.S.[1]

National Health and Nutrition Examination Survey data suggest 47.6% of seniors over the age of 75 are on a statin drug.[2] Lipitor — which is just one of several brand name statin drugs — is one of the most profitable drugs in the history of medicine.[3,4]

Collectively, statins have earned over $1 trillion since they were introduced.[5] This, despite their being off patent. There is simply no doubt that selling them is big business with major financial incentives to distort the truth to continue their sales.

Statin recommendations have become fairly complex, as they're recommended for various age groups under different circumstances, and whether they're used as primary prevention of cardiovascular disease (CVD), or secondary prevention. Guidelines also vary slightly depending on the organization providing the recommendation and the country you're in.[6]

In the U.S., the two guidelines available are from the U.S. Preventive Services Task Force (USPSTF),[7] and the American College of Cardiology and American Heart Association.[8,9] The USPSTF guidelines recommend using a statin for the primary prevention of CVD when a patient:[10]

- Is between the age of 40 to 75
- Has one or more CVD risk factors (dyslipidemia, diabetes, hypertension or smoking)
- Has a calculated 10-year risk of a cardiovascular event of 10% or greater

In secondary prevention of CVD, statins are "a mainstay," according to the Journal of the American College of Cardiology.[11] Secondary prevention means the drug is used to prevent a recurrence of a heart attack or stroke in patients who have already had one.

Regulators' Role Questioned

A February 2020 analysis[12] in BMJ Evidence-Based Medicine (paywall) brings up the fact that while the use of statins in primary prevention of CVD "has been controversial" and there's ongoing debate as to "whether the benefits outweigh the harms," drug regulators around the world — which have approved statins for the prevention of CVD — have stayed out of the debate. Should they? The analysis goes on to note:

> *"Our aim was to navigate the decision-making processes of European drug regulators and ultimately request the data upon which statins were approved. Our findings revealed a system of fragmented regulation in which many countries licensed statins but did not analyze the data themselves.*
>
> *There is no easily accessible archive containing information about the licensing approval of statins or a central location for holding the trial data. This is an unsustainable model and serves neither the general public, nor researchers."*

Have We Been Misled by the Evidence?

In her 2018 peer-reviewed narrative review,[13] "Statin Wars: Have We Been Misled About the Evidence?" published in the British Journal of Sports Medicine, Maryanne Demasi, Ph.D., a former medical science major turned investigative health reporter, delves into some of these ongoing controversies.

> *"A bitter dispute has erupted among doctors over suggestions that statins should be prescribed to millions of healthy people at low risk of heart disease. There are concerns that the benefits have been exaggerated and the risks have been underplayed.*
>
> *Also, the raw data on the efficacy and safety of statins are being kept secret and have not been subjected to scrutiny by other scientists. This lack of transparency has led to an erosion of public confidence.*

> *Doctors and patients are being misled about the true benefits and harms of statins, and it is now a matter of urgency that the raw data from the clinical trials are released,"* Demasi writes.[14]

While Demasi's paper is behind a paywall, she reviews her arguments in the featured video above. Among them is the fact that the "statin empire" is built on prescribing these drugs to people who really don't need them and are likely to suffer side effects without getting any benefits.

For example, some have recommended statins should be given to everyone over the age of 50, regardless of their cholesterol level. Others have suggested screening and dosing young children.

Even more outrageous suggestions over the past few years include statin "'condiments' in burger outlets to counter the negative effects of a fast food meal,'" and adding statins to the municipal water supply.

Simple Tricks, Big Payoffs

Medical professionals are now largely divided into two camps, one saying statins are lifesaving and safe enough for everyone, and the other saying they're largely unnecessary and harmful to boot. How did such a divide arise, when all have access to the same research and data?

Demasi suggests that in order to understand how health professionals can be so divided on this issue, you have to follow the money. The cost of developing and getting market approval for a new drug exceeds $2.5 billion. "A more effective way to fast-track company profits is to broaden the use of an existing drug," Demasi says, and this is precisely what happened with statins.

By simply revising the definition of "high cholesterol," which was done in 2000 and again in 2004, millions of people became eligible for statin treatment, without any evidence whatsoever that it would actually benefit them.

As it turns out, eight of the nine members on the U.S. National Cholesterol Education Program panel responsible for these revisions had "direct ties to statin manufacturers," Demasi says, and that public revelation sowed the first seed of suspicion in many people's minds.

Skepticism ratcheted up even more when, in 2013, the American College of Cardiology and AHA revised their statin guideline to include a CVD risk calculation rather than a single cholesterol number. U.S. patients with a 7.5% risk of developing CVD in the next 10 years were now put on a statin. (In the U.K., the percentage used was a more reasonable 20%.)

This resulted in another 12.8 million Americans being put on statin treatment even though they didn't have any real risk factors for CVD. Worse, a majority of these were older people without heart disease — the very population that stand to gain the least from these medications.

What's worse, 4 of 5 calculators were eventually found to overestimate the risk of CVD, some by as much as 115%, which means the rate of overprescription was even greater than previously suspected.

Industry Bias

While simple revisions of the definitions of high cholesterol and CVD risk massively augmented the statin market, industry-funded studies have further fueled the overprescription trend. As noted by Demasi, when U.S. President Ronald Reagan cut funding to the National Institutes of Health, private industry moved in to sponsor their own clinical trials.

The vast majority of statin trials are funded by the manufacturers, and research has repeatedly found that funding plays a major role in research outcomes. It's not surprising then that most statin studies overestimate drug benefits and underestimate risks.

Demasi quotes Dr. Peter Gøtzsche, a Danish physician-researcher who in 1993 co-founded the Cochrane Collaboration and later launched the Nordic Cochrane Centre:

> *"When drug industry sponsored trials cannot be examined and questioned by independent researchers, science ceases to exist and it becomes nothing more than marketing."*

"The very nature of science is its contestability," Demasi notes. "We need to be able to challenge and rechallenge scientific results to ensure they're reproducible and legitimate." However, there's been a "cloud of secrecy" around clinical statin trials, Demasi says, as the raw data on side effects have never been released to the public, nor other scientists.

The data are being held by the Cholesterol Treatment Trialists (CTT) Collaboration at CTSU Oxford, headed by Rory Collins, which periodically publishes meta-analyses of the otherwise inaccessible data. While the CTT claims to be an independent organization, it has received more than £260 million from statin makers.

Inevitably, its conclusions end up promoting wider use of statins, and no independent review is possible to contest or confirm the CTT Collaboration's conclusions.

Tricks Used to Minimize Harms in Clinical Trials

As explained by Demasi, there are many ways in which researchers can influence the outcome of a drug trial. One is by designing the study in such a way that it minimizes the chances of finding harm. The example she gives in her lecture is the Heart Protection Study.

Before the trial got started, all participants were given a statin drug for six weeks. By the end of that run-in period, 36% of the participants had dropped out due to side effects or lack of compliance. Once they had this "freshly culled" population, where those suffering side effects had already been eliminated, that's when the trial actually started.

Now, patients were divided into statin and placebo groups. But since everyone had already taken a statin before the trial began, the side effects found in the statin and placebo groups by the end of the trial were relatively similar.

In short, this strategy grossly underestimates the percentage of the population that will experience side effects, and this "may explain why the rate of side effects in statin trials is wildly different from the rate of side effects seen in real-world observations," Demasi says.

Deception Through Statistics

Public opinion can also be influenced by exaggerating statistics. A common statistic used to promote statins is that they lower your risk of heart attack by about 36%.[15] This statistic is derived from a 2008 study[16] in the European Heart Journal. One of the authors on this study is Rory Collins, who heads up the CTT Collaboration.

Table 4 in this study shows the rate of heart attack in the placebo group was 3.1% while the statin group's rate was 2% — a 36% reduction in relative risk. However, the absolute risk reduction — the actual difference between the two groups, i.e., 3.1% minus 2% — is only 1.1%, which really isn't very impressive.

In other words, in the real world, if you take a statin, your chance of a heart attack is only 1.1% lower than if you're not taking it. At the end of the day, what really matters is what your risk of death is the absolute risk. The study, however, only stresses the relative risk (36%), not the absolute risk (1.1%).

As noted in the review,[17] "How Statistical Deception Created the Appearance That Statins Are Safe and Effective in Primary and Secondary Prevention of Cardiovascular Disease," it's very easy to confuse and mislead people with relative risks. You can learn more about absolute and relative risk in my 2015 interview with David Diamond, Ph.D., who co-wrote that paper.

Silencing Dissenters and Fear-Based PR

Yet another strategy used to mislead people is to create the illusion of "consensus" by silencing dissenters, discrediting critics and/or censoring differing views.

In her lecture, Demasi quotes Collins of the CTT Collaboration saying that "those who questioned statin side effects were 'far worse' and had probably 'killed more people' than 'the paper on the MMR vaccine'" … "Accusing you of murdering people is an effective way [to] discredit you," she says.

Demasi also highlights the case of a French cardiologist who questioned the value of statins in his book. It received widespread attention in the French press, until critics started saying the book and resulting press coverage posed a danger to public health.

One report blamed the book for causing a 50% increase in statin discontinuation, which was predicted would lead to the death of 10,000 people. On this particular occasion, however, researchers analyzed the number of actual deaths based on national statistics, and found the actual death toll decreased in the year following the release of the book.

The authors, Demasi says, noted that it was "'not evidence-based to claim that statin discontinuation increases mortality,' and that in the future, scientists should assess 'real effects of statin discontinuation rather than making dubious extrapolations and calculations.'"

Trillion-Dollar Business Based on Flimsy Evidence

Statins, originally introduced three decades ago as secondary prevention for those with established CVD and patients with congenital and familial hyperlipidemias, have now vastly expanded thanks to the strategies summarized above.

Tens if not hundreds of millions of people are now on these drugs, without any scientific evidence to show they will actually benefit from them. As noted in the EBM analysis, "Statins for Primary Prevention: What Is the Regulator's Role?":[18]

> *"The central clinical controversy has been a fierce debate over whether their benefits in primary prevention outweigh their harms … The largest known statin*

usage survey conducted in the USA found that 75% of new statin users discontinued their therapy by the end of the first year, with 62% of them saying it was because of the side effects.

Regardless of what level of prevention statin prescription is aimed at, the proposed widening of the population to over 75s de facto includes people with multiple pathologies, whether symptomatic or not, and bypasses the distinction between primary and secondary prevention …

The CTT Collaboration estimates the frequency of myopathy is quite rare, at five cases per 10,000 statin users over five years. But others have contended that the CTT Collaboration's work 'simply does not match clinical experience' … [Muscle-related adverse events] reportedly occur with a frequency of … as many as 20% of patients in clinical practice."

Regulators Have a Duty to Create Transparency

Considering the discrepancy in reported side effects between statin trials, clinical practice and statin usage surveys, what responsibility do regulators have?

According to "Statins for Primary Prevention: What Is the Regulator's Role?"[19] regulators have a responsibility to "engage and publicly articulate their position on the controversy and make the evidence base underlying those judgments available to third parties for independent scrutiny," none of which has been done to date. The paper adds:

"Regulators holding clinical trial data, particularly for public health drugs, should make these data available in searchable format with curated and dedicated web-based resource. If national regulators are not resourced for this, pooling or centralizing resources may be necessary.

The isolation of regulators from the realities of prescribing medications based on incomplete or distorted information is not enshrined in law but is a product of a subculture in which commercial confidentiality is more important than people. This also needs to change."

Do Your Homework Before Taking a Statin

There's a lot of evidence to suggest drug company-sponsored statin research and its PR cannot be trusted, and that few of the millions of people currently taking these drugs actually benefit from them.

Some of the research questioning the veracity of oft-cited statin trials is reviewed in "Statins' Flawed Studies and Flawed Advertising" and "Statins Shown to Extend Life by Mere Days."

To learn more about the potential harms of statins, see "Statins Double Diabetes Rates," "Statins Trigger Brain Changes With Devastating Effects," and "5 Great Reasons You Should Not Take Statins."

Sources and References

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