Catalyst 'Heart of the Matter' Investigation Report

Executive Summary

Both episodes of 'The Heart of the Matter' raised matters of significant interest and importance. It is clear from the reaction to the program that many members of the audience believed that in both episodes, one side of two highly contentious issues was unduly favoured: in the first segment, whether the consumption of saturated fats raises cholesterol and causes coronary vascular disease (CVD); in the second segment, whether statins are an appropriate treatment in the care of people with elevated blood cholesterol. These are both important issues with significant public health implications where opinions differ among highly qualified scientists and medical practitioners. The subject matter was a worthwhile subject for *Catalyst* to investigate and report on.

Audience and Consumer Affairs has concluded that while the first episode was in accordance with the Code of Practice, the second episode did not adhere to section 4.5 of the Code. We have also concluded that corrective action is required to address an inaccurate statement made by Dr Demasi during an interview on *PM.*

The role of Audience and Consumer Affairs is to assess whether ABC content has been produced in accordance with the Code of Practice and ABC editorial policies; it is not to make judgements about the quality of content. However, particularly in the first episode, we believe a genuine attempt to produce content in accordance with the Code was undermined by the tone and structure of the program.

Accuracy and impartiality

<u>Episode 1 – 'Dietary Villains'</u>

The role of dietary saturated fats in heart disease has been controversial since the theory was first postulated at the beginning of the twentieth century. Notwithstanding the lack of definitive proof, mainstream medical organisations such as the National Heart Foundation believe there is enough good quality evidence to recommend a diet low in saturated and trans fats.

On the basis of their own assessment of the published literature, *Catalyst* made a judgement that there was sufficient reason to question the mainstream view to justify a program explaining the contrary view. This is a situation that calls for careful story-telling. It requires convincing the audience that the contrary viewpoint is worth considering while on the other hand explaining why the mainstream view developed and persists. In programs of this nature, the alternative theory will tend to receive more time and focus. The risks are that the effort required to convince the audience that a particular unorthodox view is worth considering will tend to minimise the attention devoted to the mainstream view, or that the program will impermissibly stray into advocacy.

An analogy can be seen in programs dealing with convicted criminals which question the basis of the conviction. The ABC has presented many such programs. They are invariably controversial. As with this episode of *Catalyst,* such programs are often accused of lacking balance and misleadingly omitting detail of the prosecution case. However, such programs have the capacity to contribute to

the public good by drawing attention to deficiencies and suggesting alternatives, potentially prompting public debate and the further examination of evidence. This is also what *Catalyst* was seeking to do.

The structure chosen by *Catalyst* began by stating that the alternative theories were both unorthodox and controversial. It then presented the evidence that challenged the orthodox view in some detail as well as including strong statements of opinion in support of that analysis by various interviewees. The program nonetheless made it clear, using a combination of interviews with the Heart Foundation's Robert Grenfell, Professor Sullivan and narration, that these theories were not accepted by mainstream organisations and that the Heart Foundation's strong advice is to lower cholesterol levels in the blood by reducing consumption of saturated fats. Consequently, it would have been clear to reasonable viewers that the unorthodox view was rejected by the country's preeminent experts.

In our judgement, the quality of the program would have been enhanced if it had more clearly communicated why the National Heart Foundation hold their views. Little substantive evidence was presented to support their perspective and the strength of the evidence that was referred to was doubted in the narration and directly challenged – and often emphatically rejected – by other contributors. Although the program did not explicitly endorse the unorthodox view, the language used by the reporter tended to add weight to the contrarian argument. The effect of this was that, for the audience, their choice was to make up their mind on the basis of evidence and opinion casting doubt on the mainstream theory on the one side and assertion backed up with little elucidated evidence on the other side. In our view, the program could have done a better job of teasing out the mainstream perspective to leave audiences better informed.

However, in our assessment this did not amount to a breach of the impartiality standard in the first episode because judgements about impartiality require a number of factors to be weighed. While there were problems with structure and tone:

1. The factual information in the program was accurately presented and the reporter has demonstrated that she diligently sought and considered a variety of views on the subject. No material inaccuracy has been demonstrated by any complainant.
2. The principal perspectives were presented.
3. Neither position was endorsed by the program.
4. Neither perspective was misrepresented.
5. The nature of the program necessitated that the unorthodox theory was given more time and explanation. The Code does not require that they receive equal time, nor that every facet of every argument is presented.

In our view, notwithstanding this conclusion that the program did not infringe standards for accuracy and impartiality, the program highlights the risks of reporting unorthodox and controversial perspectives, particularly where there is a tendency to assume that the mainstream view is well known and well understood and does not require the same level of explanation as the unorthodox position. This is a matter that should be a focus of attention while programs are in production to enhance their quality.

Episode 2 – 'Cholesterol Drug War'

In the second episode, flaws with the program's presentation did result in a finding that editorial standards had been breached.

The program's treatment of use of statins in secondary prevention focused solely on mortality benefits in a way that reinforced the view that statins were overprescribed and their benefits exaggerated. The principal relevant perspective that statins have wider benefits for this group was not properly presented. This perspective was necessary to a fair understanding of the pros and cons of statin use in this group.

Furthermore, by omitting a principal relevant view – held by the National Heart Foundation and other experts – that statins are useful in primary prevention if carefully targeted, the program had the effect of unduly favouring the perspective that statins are ineffective in primary prevention.

Our findings in relation to the second episode are necessarily different because a principal relevant perspective about the effectiveness of statins – a topic central to the program – was not presented.

PM

The National Heart Foundation also complained that Dr Demasi's statement on *PM* that it had 'signed off' on the program's evidence was untrue and deeply offensive.

While the comment was made in a live radio interview, it was nonetheless a misleading oversimplification which failed to acknowledge the clear and important areas of disagreement between the National Heart Foundation and the overall proposition being presented in the programs.

In light of this finding, corrective action is required.

Potential for harm

There is an inherent danger when any program presents criticisms of medical practices or advice that people will act without consulting experts or fully considering the consequences. That is not a reason to avoid these controversial subjects if they are in the public interest. Given the extent of cardiovascular disease in Australia, the subject matter was of significant public interest and the potential for harm was a real consideration.

We have concluded that in both episodes, appropriate steps were taken to mitigate risks.

In the first episode, the dietary advice given by the National Heart Foundation was clearly presented in the early stages of the program and reiterated by the National Heart Foundation's spokesman toward the end of the program. Along with earlier similar statements by Dr Grenfell and Professor Sullivan, this alerted viewers to the fact that health authorities consider immoderate consumption of

saturated fats to be unhealthy. The advice of these health authorities that polyunsaturated fats should replace saturated fats in the diet was also clearly presented.

These steps were further reinforced in the second program, as the potential for people to decide not to take prescribed medication was a risk. A voice over prior to and at the conclusion of the episode advised viewers that the views expressed in the program were not intended as medical advice and that they should consult with their doctors regarding medications. The importance of seeking medical advice before discontinuing medication was also reiterated by Professor Sullivan in a grab that was included in the broadcast program.

Recommended remedy

For *Catalyst,* the core problem identified in this investigation was omission of important information. Steps should now be taken by the program to provide the necessary additional information to remedy this. We suggest it would be appropriate for additional material to be made available on the special 'Heart of the Matter' program website. We also recommend that a future edition of the program refers to 'The Heart of the Matter', notes that an investigation has concluded that further important information about statins needed to be provided, and refers viewers to information available on the program website. The program is currently off air, scheduled to return later in 2014. Information can be added to the program website and the ABC Corrections page prior to an announcement being made on the program, if this is necessary.

For *PM,* we recommend that an appropriate Editor's Note be added to the program transcript to acknowledge the inaccuracy, and an entry be made on the ABC Corrections page.

Investigation Report

Introduction

'The Heart of the Matter', broadcast on *Catalyst* on 24 and 31 October 2013, examined two closely related but different issues. Firstly, whether there is a causal link between dietary saturated fat intake, cholesterol and heart disease and, secondly, whether cholesterol-lowering drugs, known as statins, are an effective preventative treatment for heart disease.

The peak health bodies in Australia generally believe the answer to both questions is 'yes' based on the weight of available evidence.

However, there is a legitimate debate about those conclusions. Reputable medical scientists dispute the significance of the link between dietary fat intake, cholesterol and heart disease and claim the overall benefit of statins, particularly in the primary care of people at risk of heart disease, is exaggerated or non-existent.

Catalyst analysed the evidence and came to strong conclusions in relation to some aspects of the debate. The program describes the aims of the two episodes as follows:

> 'The aim of the program in part 1 was to challenge the long-held beliefs that saturated fat and cholesterol cause heart disease. From the evidence presented in the program, *Catalyst* put forward a compelling case to cast doubt over the intense focus that has been given to the role of cholesterol in heart disease. The food and drug industry has profited significantly from the dietary and drug guidelines put together by the Heart Foundation. *Catalyst* highlighted the lack of evidence in dietary studies for blaming heart disease on saturated fats and cholesterol. The Heart Foundation conceded that the dietary trials are complex and it is impossible to "conclusively" prove that saturated fat causes heart disease by raising cholesterol.
>
> The aim of Part 2 was to highlight the over-prescription of medications to people who won't benefit. Whilst cholesterol lowering medications (statins) have been beneficial in secondary prevention, there is intense debate over whether these drugs should be prescribed in primary care. *Catalyst* reported on the most reliable and independent scientific evidence (TheNNT.com) in a responsible and balanced manner. The program also highlighted that the marketing of these drugs, together with health messages, has exaggerated the benefits of statins, it has underplayed their risks and has led to the widespread prescription of these drugs to people who won't live any longer. In primary prevention (those that haven't had a heart attack or stroke), statins may prevent one disease but they equally increase the risk of another life threatening disease so overall, there is not benefit for the patient.'

All the complaints we are considering allege *Catalyst* presented the evidence in an unbalanced manner. Many claim the impact has been to expose people to the risk of actual harm in that they were encouraged to cease medication and some complaints allege specific instances where factual material or perspectives have been misrepresented. Some complaints also allege that on the *PM* program on 31 October, Maryanne Demasi misrepresented the National Heart Foundation.

Editorial standards

The ABC's Editorial Policies permit content-makers to come to strong conclusions on issues of public interest and to challenge commonly held views, so long as their work is impartial, fair and based on demonstrable evidence.

Impartiality

The Editorial Policies make clear that the ABC aims to apply its impartiality standard as objectively as possible, guided by the following hallmarks of impartiality:

- a balance that follows the weight of evidence;
- fair treatment;
- open mindedness; and
- opportunities over time for principal relevant perspectives on matters of contention to be addressed.

The Editorial Policies further provide that assessing the impartiality due in given circumstances requires consideration in context of all relevant factors including:

- the type, subject and nature of the content;
- the circumstances in which the content is made and presented;
- the likely audience expectations of the content;
- the degree to which the matter to which the content relates is contentious;
- the range of principal relevant perspectives on the matter of contention; and
- the timeframe within which it would be appropriate for the ABC to provide opportunities for the principal relevant views to be expressed, having regard to the public importance of the matter of contention and the extent to which it is the subject of current debate.

Having considered these factors, our view is that these editions of *Catalyst* program were obliged to observe high standards of impartiality. We regard the following as particularly relevant:

- *Catalyst* is a highly regarded science program which reaches a wide audience. Over a long period, it has developed a reputation for communicating complex scientific ideas in a straightforward, easy to understand manner. It describes itself as the ABC's flagship television science program.
- The subject matter of the two programs was a matter of considerable public importance, dealing with the serious issue of the causes of cardiovascular disease and its treatment. Cardiovascular disease is a leading cause of death in Australia,[1] making this an issue of relevance to a large and diverse audience. Some 2 to 3 million Australians are currently

[1] http://www.heartfoundation.org.au/information-for-professionals/data-and-statistics/Pages/default.aspx.

estimated to be taking cholesterol-lowering drugs in order to prevent heart disease, making statins the most commonly prescribed drugs in Australia.[2]

- Given the importance of the subject matter and the reputation of the program, audiences were likely to expect a high degree of accuracy, fairness and impartiality. They would not expect the ABC to advocate for a particular position, but to present the facts and perspectives fairly in order to assist viewers to make up their own minds.

- As indicated by *Catalyst* the programs set out to challenge the mainstream, orthodox view of the role of cholesterol in heart disease, and the use of statins in preventative care. The program makers were aware that the core of the material they were presenting was in contrast to the views of peak health bodies in Australia, such as the National Heart Foundation. The program's challenging of these views, combined with the potential for the program to influence individual viewers' decisions about their own approach to heart health, ensured that the programs would be particularly contentious. It is likely that many viewers would not have previously been aware of the debate about these matters in scientific circles and that they would be hearing about the issue for the first time and beginning to form their views on these debates based on the material presented in the *Catalyst* program.

- While the issue of cardiovascular disease and its prevention is dealt with from time to time on ABC programs, it is not a common subject for coverage. This placed a greater responsibility on the program makers to include the principal relevant perspectives on the matters of contention discussed.

Relevant editorial standards for impartiality:

> *4.1 Gather and present news and information with due impartiality.*
>
> *4.2 Present a diversity of perspectives so that, over time, no significant strand of thought or belief within the community is knowingly excluded or disproportionately represented.*
>
> *4.4 Do not misrepresent any perspective.*
>
> *4.5 Do not unduly favour one perspective over another.*

Accuracy

The ABC's Editorial Policies require reasonable efforts to be made to ensure accuracy in fact-based content. The ABC gauges these efforts by reference to:

- the type, subject and nature of the content;

- the likely audience expectations of the content;

- the likely impact of reliance by the audience on the accuracy of the content; and

[2] http://www.smh.com.au/national/health/miracle-drugs-put-thousands-at-risk-20120229-1u3ia.html, http://www.abc.net.au/health/library/stories/2013/11/01/3881358.htm .

- the circumstances in which it was made and presented.

These points share many characteristics with those relevant to an assessment of impartiality, as discussed above. Consideration of these factors again leads to the conclusion that for *Catalyst*, a high level of effort to ensure accuracy would reasonably be expected.

Relevant editorial standards for accuracy:

> *2.1 Make reasonable efforts to ensure that material facts are accurate and presented in context.*
>
> *2.2 Do not present factual content in a way that will materially mislead the audience. In some cases, this may require appropriate labels or other explanatory information.*

Harm

The ABC's Editorial Policies require that any content likely to cause harm is justified by the editorial context (7.1). No complainants seriously suggested that the *Catalyst* program should not have tackled this subject. While many complainants were dissatisfied with the overall messages conveyed by the program, there was general support for the view that programs which seriously evaluate scientific evidence play a valuable role in informing the public. Many complainants, however, took issue with the way that *Catalyst* dealt with the evidence. These complainants were concerned that there was real potential for *Catalyst* to cause harm by promoting dangerous behaviours that run counter to the advice given by peak health bodies – such as adherence to a statin medication regime. For these complaints, we have considered the program's compliance with the most relevant editorial standard:

> *7.6 Where there is editorial justification for content which may lead to dangerous imitation or exacerbate serious threats to individual or public health, safety or welfare, take appropriate steps to mitigate those risks, particularly by taking care with how content is expressed or presented.*

Complaints

1 Ancel Keys' population studies were misrepresented – Part I – Code of Practice section 2.2

Complaint

Complainants allege that the section on Keys is inaccurate and misleading. The section implies that Keys relied on the six country study whereas it was one of several studies such as the seven countries study. The story accuses Keys of cherry-picking data and states that different choices would provide a different result. However, including all 22 countries still provides a strong correlation. The suggestion that Keys withheld and fudged data implies an attempt to deceive and is misleading.

Transcript

> ***NARRATION**: Aside from people with a genetic condition, like familial hypercholesterolemia, diet has long been the focus of how we can lower our cholesterol. The idea that saturated fat clogs your arteries by raising cholesterol first gained traction in the '50s. American nutritionist Ancel Keys became intrigued with the soaring rates of heart disease after World War II.*
>
> ***Ancel Keys**: The facts are simple. You know the chief killer of Americans is cardiovascular disease.*
>
> ***NARRATION**: He compared the rates of heart disease and fat consumption in six countries. It was almost a perfect correlation - the more fat people ate, the higher the rates of heart disease. Except, there was just one problem. Keys withheld data for 16 other countries. Later, when researchers plotted all 22 countries, the correlation wasn't so perfect. Dr Michael Eades is critical of the way Ancel Keys excluded countries that didn't fit his hypothesis.*
>
> ***Dr Michael Eades**: He more or less cherrypicked countries. You could show just the opposite. You could show that the more saturated fat people ate, the less heart disease they had, if you cherrypicked the right countries.*
>
> ***NARRATION**: Dr Eades says that even if fat consumption trends in the same direction as heart disease, it doesn't prove anything.*
>
> ***Dr Michael Eades**: Just because there's a correlation, doesn't mean that there's causation. It's like people who are fat have big belts, but that doesn't mean that if you buy smaller belts, you won't be fat. I mean, that's not the causation. That's what these observational studies show - it's just a correlation.*
>
> ***Dr Ernest Curtis**: The classic study by Ancel Keys is a textbook example of fudging the data to get the result that you want out of a study. And, unfortunately, there's a lot of that that goes on.*

Assessment

The program's references to Ancel Keys and the 6 countries study included both factual material and opinion.

While Keys was not the first to associate cholesterol with cardiovascular disease, it is fair to say – as the *Catalyst* program did – that the theory *'gained traction in the 50's'* largely as a result of his work. It was this early popularisation of the cholesterol theory that the program was drawing attention to here; the program was not attempting to provide a comprehensive analysis of Keys' work. While many commentators would probably rate the later 7 countries study as more influential than the 6 countries study (actually called 'Atherosclerosis, A Problem in Newer Public Health')[3], the results of the 7 countries study were not published until many years later in the 1980s and were not relevant to a discussion of the emergence of this theory in the 1950s.

We are satisfied that the program's factual references to the 6 countries study were accurate: it is true that data for the 16 additional countries was not included in the analysis and it is fair to say that '*when researchers plotted all 22 countries, the correlation wasn't so perfect'*. *Catalyst* has explained that this latter statement refers to the work of Yerushalmy and Hilleboe, the two scientists who exposed the full set of country data. Yerushalmy and Hilleboe said that while the full data set reached statistical significance (r value of 0.59) showing '*some association',* Keys had '*greatly exaggerated the importance of the association*'.[4] Keys did explain that he omitted some countries because the significant short-term effects of WWII on the diets of populations in German occupied territories made comparison difficult. However, this was not a material point in a discussion of the differing strength of association when the full 22 countries were included.

The extent to which Keys '*cherry picked'* or '*fudged'* his data is a critique and is a matter of opinion rather than fact. It was presented as opinion in the story, shown as the views of interviewees who were critical of the cholesterol theory.

In considering whether the program's references to Keys' work complied with impartiality standards, we have considered the twofold impact of this section on the program overall. In our view, the discussion about Keys' early contributions to this theory illustrated, firstly, that correlation doesn't prove causation; secondly, that Keys' early work doesn't demonstrate that a convincing correlation necessarily exists in the first place. The first message neglects to point out that while correlation does not prove causation it can be very strong evidence of causation. The second emphasises a position sceptical of the association shown by Keys over those who maintain that Keys did demonstrate a clear relationship.

The issue of causation was a significant theme of this episode, stretching well beyond the discussion of Keys' earlier work. It is better considered in relation to complaint 6.

In considering the program's treatment of the strength of association demonstrated by Keys, it is relevant to note that the ABC's editorial standards for impartiality do not require every facet of very argument to be presented. The broad point that the program was making – that the medical

[3] See for instance http://www.nytimes.com/2004/11/23/obituaries/23keys.html?_r=0.
[4] An account of this controversy is provided by Henry Blackburn (a colleague of Keys) and Darwin Labarthe in their article, 'Stories from the Evolution of Guidelines for Causal Inference in Epidemiologic Associations: 1953-1965', published in the *American Journal of Epidemiology,* http://aje.oxfordjournals.org/content/176/12/1071.full.pdf+html.

community's initial acceptance of the link between cholesterol and heart disease was based on methodologically questionable correlations and without proof of causality – is supported by the weight of evidence.

The extent to which Keys deliberately misrepresented his data is not material to the program and it was not necessary for alternative perspectives to be presented.

Conclusion – No breach of section 2.2

2 Mediterranean Diet & The Lyon Diet Heart study – Part I – Code of Practice section 2.2

Did the program accurately describe the Lyon Diet Heart study?

Complaint

Professor Sullivan writes that it was misleading to ascribe the benefits of the Mediterranean diet to n-3 fatty acids, antioxidants and low sugar without revealing that, compared to the prudent control diet, the Mediterranean diet was also low in saturated fats, a point he had drawn the program's attention to prior to the broadcast.

A second complainant (C60949-13) asserts that the program wrongly referenced the Lyon study as evidence that cholesterol is not implicated in heart disease, when the final report of the study clearly states the opposite.

Transcript

> ***NARRATION****: There is one diet that stands out from the rest - the Lyon Diet Heart Study, which touted the benefits of a Mediterranean diet. Remarkably, after several years, those on the Mediterranean diet had a whopping 76% less deaths from heart attacks.*
>
> ***Dr Maryanne Demasi****: So why did the Mediterranean diet get such a spectacular result when all the others had failed? I'll explain why later. But one of the most interesting things to come from that study went virtually unnoticed.*
>
> ***Dr Jonny Bowden****: Here's the part that nobody talks about. See, you think that in the group that had the double-digit reduction in heart disease, their cholesterol levels must have plummeted, right? Their cholesterol levels didn't budge. Both groups had the same cholesterol levels, except one group just stopped dying. So, so much for the relationship between cholesterol and the risk for heart disease.*

Later

> ***NARRATION****: This is thought to be why the Mediterranean diet was so successful. It was higher in omega-3 fats, not to mention it was low in refined carbohydrates like sugar, and rich in antioxidants.*

Assessment

There are two issues here: whether the program should have made clear that the experimental diet in the Lyon study was low in saturated fat, and whether the program wrongly suggests that the Lyon study can be used to support a view that cholesterol is not implicated in heart disease.

Saturated fat

On the first issue, it is clear that the researchers in the Lyon study deliberately set out to test the Mediterranean-type diet compared to a 'prudent Western-type diet', which was also considered to be low fat. It is correct that subjects in the Lyon study's experimental group reported lower levels of total fat intake and saturated fat intake than the control subjects – total fat: experimental subjects reported an average of 30.4% of daily calories provided by lipids compared to 33.6% in the control group ($p<0.002$); saturated fat: experimental subjects reported an average of 8.0% of daily calories supplied by saturated fat compared to 11.7% for the control group ($p < 0.0001$).[5] The initial report of the Lyon study made clear that *'[t]he experimental group consumed significantly less lipids, saturated fat, cholesterol and linoleic acid but more oleic and alpha-linolenic acids'*.[6] However, the strongest dietary message that the authors derived from the study was not related to its saturated fat content. In their concluding statement summarising the effect of the dietary intervention, the authors wrote: '*An alpha-linolenic acid-rich Mediterranean diet seems to be more efficient than presently used diets in the secondary prevention of coronary events and death'.*[7] These '*presently used diets'* are diets low in saturated fat.

The orthodox theory that the program was challenging is that intake of dietary saturated fat causes increased LDL cholesterol which causes heart disease. If this hypothesis were correct, we would expect to see lower LDL cholesterol in the Lyon experimental group who consumed less saturated fat, but this did not occur. Telling viewers that the Mediterranean diet used in the Lyon study was low in saturated fat would not have offered support to the orthodox viewpoint, and we therefore conclude that it was not materially misleading to viewers for the program to omit mention of this fact.

Cholesterol

Dr Jonny Bowden used the results of the Lyon study to dismiss the claimed link between cholesterol and heart disease:

> *'Here's the part that nobody talks about. See, you think that in the group that had the double-digit reduction in heart disease, their cholesterol levels must have plummeted, right? Their cholesterol levels didn't budge. Both groups had the same cholesterol levels, except one group just stopped dying. So, so much for the relationship between cholesterol and the risk for heart disease.'*

This statement included both fact and opinion. The facts asserted were that cholesterol levels in the diet and control groups did not vary, but that members of one group died less frequently. The opinions asserted were that this finding went unremarked upon and that the Lyon study put to rest

[5] http://circ.ahajournals.org/content/99/6/779.full.pdf+html, table 3, p 782.
[6] http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(94)92580-1/abstract, p 1454.
[7] http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(94)92580-1/abstract p 1454.

the claimed relationship between cholesterol and risk of heart disease. Ordinary reasonable viewers would understand these latter two points to be conclusions of a contestable kind. The accuracy standards do not apply to statements of opinion.

According to the intermediate report of the Lyon study, '*a reduction in coronary events and cardiac deaths of close to 70% was achieved without a reduction of serum cholesterol, triglycerides, or an increase in HDL compared to controls'*.[8] The final report of the Lyon study states that at their final visit, subjects in the control group had an LDL cholesterol of 4.23 mmol/L whereas subjects in the experimental group had an LDL cholesterol of 4.17 mmol/L.[9] Editorialising in the same issue of *Circulation* in which the final report of the Lyon study was published, Dr Alexander Leaf commented:

> '*At a time when health professionals, the pharmaceutical industries, and the research funding and regulatory agencies are almost totally focused on lowering plasma cholesterol levels by drugs, it is heartening to see a well-conducted study finding that relatively simple dietary changes achieved greater reductions in risk of all-cause and coronary heart disease mortality in a secondary prevention trial than any of the cholesterol-lowering studies to date. This is emphasized by the finding that the unprecedented reduction in risk of CHD was not associated with differences in total cholesterol levels between the control and experimental groups…'*.[10]

While the Lyon study found that mortality rates changed even when cholesterol levels did not, it did not dismiss the relevance of cholesterol as a risk factor in heart disease. The authors wrote:

> '*As expected, total cholesterol and leukocyte count were major independent and joint predictors of recurrence, along with the dietary pattern … [E]ach increase of 1 mmol/L of total cholesterol increased the risk of recurrence by 20% to 30% [T]he data indicate that neither the Mediterranean dietary pattern nor any major bias has altered the usual and expected relationships between the major risk factors of CHD and recurrence'*.[11]

And:

> '*Major traditional risk factors, such as high blood cholesterol and blood pressure, were shown to be independent and joint predictors of recurrence, indicating that the Mediterranean dietary pattern did not alter, at least qualitatively, the usual relationships between risk factors and recurrence.'*[12]

Dr Alexander Leaf commented:

> *'This study does not contradict the importance of plasma cholesterol in the genesis of CHD – the authors measured and acknowledge its contribution to the outcomes in their study – but it indicates that there are other powerful risk factors within the realm of diet that must be*

[8] http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(94)92580-1/abstract, p 1458.
[9] http://circ.ahajournals.org/content/99/6/779.full.pdf+html, table 3, p 782.
[10] http://circ.ahajournals.org/content/99/6/733.full.pdf+html, p 733.
[11] http://circ.ahajournals.org/content/99/6/779.full.pdf+html, p 784.
[12] http://circ.ahajournals.org/content/99/6/779.full.pdf+html, p 779.

considered if we are to achieve maximal dietary benefits in reducing this number 1 cause of mortality in the world today'.[13]

Dr Bowden's point that blood cholesterol levels did not differ between the experimental and control groups is supported by the evidence. What the study seems to have demonstrated is that a Mediterranean diet reduces mortality independent of changes in cholesterol, while simultaneously showing that cholesterol remains an independent predictor of cardiovascular events. Accepting that the experimental diet was lower in saturated fat than the control diet, it would be expected that the experimental group who died in lower numbers would also have lower cholesterol. But the study did not show this. In effect, this finding from the Lyon study adds support to the anecdotal observations made by Dr Curtis and Dr Sinatra earlier in the program. It suggests that something more complex is at work in the relationship between diet and heart disease, and that factors other than cholesterol are associated with a greater mortality benefit.

We are satisfied that the factual content was not presented in a way that would materially mislead the audience.

Conclusion – No breach of 2.2

3 Misrepresentation of the composition of margarine in Australia – Part I – Code of Practice sections 2.1 & 2.2

Complaint

The allegation is that it is misleading in an Australian context to say margarine is a '*trans fat-laden crappy manufactured product*' and '*When vegetable oils are used to manufacture margarine, they undergo a process called partial hydrogenation, which results in the formation of industrial trans fats, and everybody agrees they're bad for you*' because that is not generally the case here and ordinary viewers would have assumed that this describes margarine in Australia and is, therefore, misleading.

Transcript

***NARRATION**: The more recent advice is to replace saturated fat with unsaturated fats in order to lower the risk of heart disease. For example, swapping butter with margarine.*

***Dr David Sullivan**: It's very hard to find any positives about butter in term of its impact on cardiovascular disease.*

***NARRATION**: But this advice still receives its fair share of opposition.*

***Dr Jonny Bowden**: Margarine is the perfect example of the stupidest nutritional swap-out in history. We had this trans fat-laden crappy manufactured product that we were eating because we were so phobic about saturated fat and cholesterol.*

[13] http://circ.ahajournals.org/content/99/6/733.full.pdf+html, p 733.

***Dr Stephen Sinatra**: To switch to polyunsaturated fats with the vegetable oils, that's horrific advice. The polyunsaturated fats, the vegetable oils, these omega-6 oils, are inflammatory because they're very prone to oxidation.*

***Dr Maryanne Demasi**: Have we been given the wrong advice?*

***Dr Michael Eades**: We've absolutely been given the wrong advice. People became afraid of saturated fat, so they said, 'OK, we've got to do something to replace the saturated fats, and so let's do it with vegetable oils.' Well, vegetable oils don't have the same cooking qualities that saturated fats do. Polyunsaturated fats have a lot of double bonds in them, and double bonds are prone to free radical attack.*

It becomes a rancid fat, and it becomes really bad for you. Saturated fats, on the other hand, have no double bonds. That's why they're incredibly stable. That's why they're great for cooking. That's why they're great for frying. And that's why they don't really perpetuate free radical cascades in the body, because they're inert fats.

***NARRATION**: Dr Eades says butter and coconut are not harmful to your health, and recommends those fats over the omega-6 vegetable oils. When vegetable oils are used to manufacture margarine, they undergo a process called partial hydrogenation, which results in the formation of industrial trans fats, and everybody agrees they're bad for you.*

It's important to look for products that have them removed, although Australia doesn't have mandatory labelling of them. Junk food, for example, is riddled with industrial trans fats. The omega-3s, another type of polyunsaturated fat - found in fish, for example - are thought to counter the inflammatory effects of omega-6s.

***Dr Michael Eades**: The two of them are kind of like the accelerator and a brake pedal on a car, and if they're in balance things operate smoothly. I mean, you don't want too much anti-inflammatory, you don't want too much pro-inflammatory. Because of the advent of vegetable oils, we now have tons of omega-6 fats, and, really, very little omega-3 fats.*

Assessment

While there was no factually incorrect statement made by the program about trans fats and margarine, complaints have alleged that the context was misleading.

Catalyst explained:

> *'There was a time when margarines contained transfats. According to nutritionist Catherine Saxelby most Australian margarines now have little transfats (prob since the mid 1990's). However, there are still margarines on the market – albeit in the minority – that do have transfats, (e.g. cooking margarines and generic brand margarines) which is why we clearly stated "it is important to look for margarines that have them removed". This way, the audience knows to be wary of food labels.'*

We have considered information from a range of sources about the extent to which Australian margarines contain trans fats and the advice given to consumers. For example:

- Advice from the CSIRO includes the following:

  > '*Although the major [margarine] brands in Australia are trans free, some 'home' brands still contain a significant amount so check their labels*.'[14]

- The Dieticians' Association of Australia advises:

  > ***Trans fats in margarines***
  >
  > *It is often thought that margarines contain high levels of trans fats. This is not the case in Australia. Fortunately, Australian manufacturers are able to remove most of these trans fats during the manufacturing process. Margarine's which contain unsaturated fats (like those made with canola or olive oil) can be a healthy source of fat in the diet. Remember to always read the label to find out more about the individual product.*
  >
  > ***Food labels***
  >
  > *Australian manufacturers are not required to include trans fats on food labels unless they make a nutrition claim about cholesterol, saturated or unsaturated fat, or trans fatty acids. It is important to be aware of the types of foods that may contain trans fatty acids, as it may not be obvious by looking at labels on food packages.*

- In 2005 *Choice* examined the properties of a range of butters, margarines and spreads.[15] Products with a trans fat content of between 6-8% were not uncommon and the brands providing these spreads would be familiar to many Australian consumers – Coles, Bi-Lo, Black and Gold, IGA, etc. While this assessment is dated, it was conducted in a period since the 1990s, the time at which most trans fats are said to have been removed from Australian margarines.

The take-out message from the program was that consumers should check the label and look for products that have had trans fats removed. On balance, given that some margarines in Australia do continue to include trans fats, we are satisfied that the program was not materially misleading in this context.

Conclusion – No breach of section 2.2

[14] http://www.csiro.au/Outcomes/Health-and-Wellbeing/Prevention/Margarine.aspx.
[15] http://www.choice.com.au/~/media/Files/Food%20and%20health/Food%20and%20drinks/Butter%20and%20marg/0501Spreads.ashx.

4 Inaccurate description of the structure of polyunsaturated and saturated fats – Part I – Code of Practice section 2.1

Complaint

"It was mentioned that those molecules which contain long chains of single carbon bonds are more stable than those containing numerous double bonded carbon groups. Students doing high-school chemistry will be able to tell you the fault in this statement."

Transcript

> ***Dr Michael Eades****: We've absolutely been given the wrong advice. People became afraid of saturated fat, so they said, 'OK, we've got to do something to replace the saturated fats, and so let's do it with vegetable oils.' Well, vegetable oils don't have the same cooking qualities that saturated fats do. Polyunsaturated fats have a lot of double bonds in them, and double bonds are prone to free radical attack. It becomes a rancid fat, and it becomes really bad for you. Saturated fats, on the other hand, have no double bonds. That's why they're incredibly stable.*

Assessment

Catalyst have provided the following explanation:

> *'"Poly" (meaning many double bonds) in polyunsaturated fatty acids (PUFA) and "mono" (meaning one double bond) in monounsaturated fatty acids (MUFA) refers to either multiple or singular double bonds in the chemical chain. Saturated fats have no double bonds in their long chain.*
>
> *The double bonds in the fatty acid make the foodstuff prone to free radical attack by oxidation which is why fish (which is polyunsaturated) goes off quickly at room temperature, but butter (which is mostly saturated fat) is more stable. Even Dr Sullivan explains this in the extended interview.'*

In his extended interview available on the program website,[16] Professor Sullivan states:

> *'I think we have some excellent substitutes for unhealthy saturated fat because in terms of oxidation, the problem lies with the fact when you've got two double bonds next to each other. However in mono unsaturated fats we only have one double bond and therefore they are resistant to oxidation. So mono unsaturated fats are a very good option to replace saturated fats in terms of oxidizability … Because the susceptibility lies with two double bonds next to each other, our n-6 fatty acids are maybe even a little bit less likely to be oxidised then our n-3 fatty acids.'*

We are unable to identify any inaccuracy in the program's reference to double bonds and stability of fats.

[16] http://www.abc.net.au/catalyst/heartofthematter/.

Conclusion – No breach of section 2.1

5 Misrepresentation of the National Heart Foundation & Dr Grenfell – Part I – Code of Practice section 2.2

Did the program misrepresent the material and statements provided to it by the NHF?

Complaint

The National Health Foundation claims that the quote, *'We agree that we are limited by the evidence base, available at this time'* was taken out of context in that it referred to comments by two epidemiologists about the limitations of research possibilities in proving a link between saturated fat intake and coronary heart disease outcomes. They claim that the National Heart Foundation was not saying that they agree evidence is '*limited*' that '*intake of saturated fats leads to an increase in blood cholesterol*'.

The National Heart Foundation also claim *Catalyst* misleadingly suggested that it only provided the program with one study, saying that *Catalyst* was referred to the Mensink meta-analysis, which referenced 60 other studies; various other analyses that confirmed the Mensink results; and to the WHO summary, which referenced a wider range of other studies.

Transcript

> ***NARRATION**: ... Two ambitious trials ...failed to prove that lowering saturated fat could lower your risk of dying from heart attack.*
>
> ***Gary Taubes**: The way the authorities responded to this ... was to claim that they must have done the study wrong...*
>
> ***NARRATION**: The National Heart Foundation of Australia defends these failures, saying that nutrition trials are just too complex.*
>
> ***Dr Robert Grenfell**: When you ask that question of 'Do dietary fats increase heart disease?', you're sort of trying to negate all the other risk factors that, in fact, actually also cause heart disease. So, to imagine creating a study that would prove that conclusively is virtually impossible.*
>
> ***Dr Maryanne Demasi**: So, if they can't prove it, on what basis have they decided that saturated fat is bad for us?*
>
> ***Presenter, in advertisement**: Eat too much fatty food and you risk a high level of blood cholesterol building up in your arteries. Eat sensibly.*
>
> ***Dr Robert Grenfell**: Meta analyses have, in fact, actually shown that, you know, we can say with convincing evidence that intake of saturated fats leads to an increase in blood cholesterol.*

> ***Dr Maryanne Demasi****: An extensive review of the literature showed that the data was highly inconsistent. In fact, there were many long-term studies that refute the idea that saturated fat raises cholesterol. So I approached the National Heart Foundation for further evidence. They said the data was complex. They cited one study which showed only certain types of saturated fat could raise bad cholesterol, but it also raised good cholesterol. In the end they concluded - 'We agree that we are limited by the evidence base, available at this time.*'

Assessment

In her email to the National Heart Foundation Maryanne Demasi stated that she had read several scientific studies looking for support for Dr Grenfell's statement in the interview that '*saturated fat raises cholesterol*'. She said she had found the evidence '*weak*' and that '*the literature does not offer much support for the idea that long term saturated fat intake has a significant effect on the concentration of blood cholesterol in humans*'. She named the research she had looked at and asked for more evidence. A reply was sent on behalf of the National Heart Foundation, which did not contradict Dr Demasi. It reiterated the difficulties of proving the hypothesis conclusively and provided links to other studies and papers that, they said, provided evidence in support of the link.

Towards the middle the email said *'We agree that we are limited by the evidence base, available at this time*', which was followed by two quotes from nutritional epidemiologists pointing to the limitations of research possibilities in proving a link between saturated fat intake and coronary heart disease outcomes. These quotes essentially reiterated the point Dr Grenfell had made in the program:

> ***Dr Robert Grenfell****: When you ask that question of 'Do dietary fats increase heart disease?', you're sort of trying to negate all the other risk factors that, in fact, actually also cause heart disease. So, to imagine creating a study that would prove that conclusively is virtually impossible.*

Later, in its summary of the email's main points, the National Heart Foundation officer wrote, '*There are inherent limitations in nutrition research. We have to work with what we've got!'*

The original email from Dr Demasi was very clearly dealing with one specific question – does saturated fat intake raise cholesterol in humans in the long term? A normal reading in context would understand the comment made by the National Heart Foundation in its email to mean the evidence base is limited, as the story reported.

Audience and Consumer Affairs are satisfied that the quote was not taken out of context.

In relation to the reference to '*one study*', the National Heart Foundation says that this implies that they provided only one study for *Catalyst* to review when, in fact, they provided many. It is true that the email provided links to a number of different papers. However, it did highlight the Mensink study as the one scientific paper – as against general reviews such as the FAO/WHO & NHF reviews – that dealt specifically with the question *Catalyst* was asking.

In this context, it was not materially misleading to highlight the one study that was provided to address the specific question being asked during this section of the program.

Conclusion – No breach of section 2.2.

6 Undue favouring of the perspective that saturated fats do not cause heart disease by raising cholesterol – part I – Code of Practice sections 2.2 and 4.5

Complaint

The hypothesis that eating saturated fats can increase cholesterol levels which in turn can cause heart attacks is widely accepted by the medical community and is the basis for most official dietary advice. Some medical researchers and physicians believe the hypothesis is flawed – *Catalyst* presented and examined their criticisms.

Complaints, including from the National Heart Foundation, allege the analysis lacked balance and omitted critical evidence.

These are typical of the complaints that *Catalyst* did not present good quality evidence that supported the consensus view on cholesterol:

> *'It is well known that cardiovascular disease is multi-factorial - and elevated cholesterol is a statistically significant factor. There are numerous large scale studies (some of which still continue today) which statistically demonstrate this point. These statistical, peer reviewed studies and subsequent papers are what current guidelines are based on.' (C59160-13)*
>
> *'None of us argue that cholesterol is the only risk factor for coronary artery disease, but to dismiss the evidence of rigorously conducted cholesterol lowering studies, such as the 4S Study (Lancet Nov 1994), and Australia's own "LIPID" Trial (N Engl J Med 1998; 339:1349-1357 November 5, 1998),* http://www.nejm.org/doi/full/10.1056/NEJM199811053391902 *defies explanation.'(C160118-13)*
>
> *'There is conclusive evidence that cholesterol, particularly when considered in terms of its fractions (LDL and HDL), is a very significant risk factor for coronary heart disease, stroke and other forms of artery disease.' (Prof Sullivan)*

Assessment

The key issue explored in Part I is, does dietary fat, in particular saturated fat, cause or significantly contribute to heart disease? The Heart Foundation and others basically say, 'yes'.

The narration and pieces to camera overwhelmingly presented the arguments against this '*medical dogma'*.

The assessment focuses on whether the program was accurate, fair, presented principal relevant perspectives on the key matters of contention and presented a balance that follows the weight of evidence.

We think it is safe to assume that most viewers would have been aware that standard medical advice for prevention of heart disease includes avoiding or minimising consumption of saturated fats and lowering cholesterol levels. If they were not, the story told them at the head of the program:

Dr Maryanne Demasi: *The National Heart Foundation guidelines are pretty clear. We're told to reduce our saturated fat and cholesterol levels in order to reduce our risk of heart disease.*

The program clearly signalled to viewers that it would be challenging the '*medical paradigm'* that saturated dietary fat and cholesterol are the '*villains in heart disease'* because they are said to be '*artery clogging'*. In her opening piece to camera Dr Demasi said she would reveal why this hypothesis is '*being touted as the biggest myth in medical history'* and is being challenged by some medical experts. The subject of the story, therefore, was the alternative medico scientific theory.

Dr Demasi told viewers that in this episode she would be *'follow[ing] the road which led us to believe that saturated fat and cholesterol cause heart disease'* and the program broadly took a chronological, historical perspective in its examination of science underlying the so-called 'diet-heart' hypothesis. The early work of Ancel Keys was introduced and criticised for confirmation bias and for failing to establish a causative link between dietary fat consumption and deaths from coronary heart disease. The program continued:

NARRATION: *As the idea gained widespread acceptance with the public, science was left to catch up. Two ambitious trials, costing over $250 million, involving hundreds of thousands of patients, both failed to prove that lowering saturated fat could lower your risk of dying from heart attack.*

The program then sought the perspective of the National Heart Foundation:

NARRATION*: The National Heart Foundation of Australia defends these failures, saying that nutrition trials are just too complex.*

Dr Robert Grenfell*: When you ask that question of 'Do dietary fats increase heart disease?', you're sort of trying to negate all the other risk factors that, in fact, actually also cause heart disease. So, to imagine creating a study that would prove that conclusively is virtually impossible.*

In view of Dr Grenfell's concession that the link between dietary fats and heart disease was virtually impossible to prove, Dr Demasi asked on what basis the National Heart Foundation had decided that saturated fat is bad. Dr Grenfell responded:

Dr Robert Grenfell*: Meta-analyses have, in fact, actually shown that, you know, we can say with convincing evidence that intake of saturated fats leads to an increase in blood cholesterol.*

Dr Demasi then said that the data supporting this was '*highly inconsistent'* and that many long-term studies had refuted the idea that saturated fat raises cholesterol. The program then quoted Professor Sullivan in relation to dietary advice:

Associate Prof David Sullivan: *I think there are some very telling pieces of evidence which have been used to establish the importance of avoiding saturated fat. If saturated fat is completely benign, if it's actually beneficial, where's the evidence in support of that? Where's the evidence of an alternative cause? We are particularly keen to get some dietary advice, because otherwise what do we offer people?*

Later, after the program had presented an alternative '*inflammatory theory of heart disease'* which places a greater emphasis on sugar and stress as causes of heart disease, Dr Grenfell said these theories are untested and that he believes cholesterol is '*a contributor*'.

Returning to its chronological examination of the science, the program referred to the US Senate Select Committee on Nutrition and Human Needs which in 1977 issued nutritional guidelines which '*led to the creation of the food pyramid, which formed the basis of our dietary advice in the following four decades. It advised us to eat less saturated fat, mainly found in meat and dairy, recommending a diet rich in carbohydrate foods, like breads, grains and cereals.'*

More recent dietary advice had changed these recommendations, as Professor Sullivan explained:

> ***NARRATION:*** *Dr Sullivan does concede that an aspect of the food pyramid was a mistake. He says replacing fats with carbohydrates didn't help the rising obesity problem.*
>
> ***Dr David Sullivan:*** *If you replace fat with carbohydrate, you will probably be a little bit more inclined to be hungry; your insulin levels will be a bit higher, you'll have high levels of triglyceride, higher levels of glucose and less of your good cholesterol to avert problems. We certainly probably gave some advice which was a good way to avert one pathway, but people then tracked down another pathway, and that's what's led to the revision of dietary guidelines.*
>
> ***NARRATION:*** *The more recent advice is to replace saturated fat with unsaturated fats in order to lower the risk of heart disease. For example, swapping butter with margarine.*
>
> ***Dr David Sullivan:*** *It's very hard to find any positives about butter in term of its impact on cardiovascular disease.*

Finally, towards the end of the program, Dr Grenfell stated:

> **Dr Robert Grenfell:** *The Heart Foundation still suggests that a diet that substitutes saturated fats for polyunsaturated fats is one that is healthier for your heart.*

The position of the National Heart Foundation, therefore, was presented. Viewers would not have been in doubt that it supported the hypothesis that dietary intake of saturated fats can raise cholesterol which can cause heart disease, and that it recommends that unsaturated fats should replace saturated fats in the diet.

Throughout the episode, this orthodox position was vigorously contested by others who believe the cholesterol theory has been discredited. These interviewees expressed their views in strong language, calling the diet-heart hypothesis *'100% wrong', 'a bold-faced lie',* a *'myth'*, and describing the National Heart Foundation's recommendation that saturated fats should be replaced with polyunsaturated fats as *'horrific'* and (in relation to margarine specifically) *'the stupidest nutritional swap-out in history'.* The program did not present the sceptics' hypothesis as fact or as the opinion of the ABC. Nonetheless, where the program did make conclusions about the evidence, it supported the view that the causal link between saturated fat intake and heart disease is unproven, and that dietary changes have not shown a mortality benefit.

Does the weight of evidence support those conclusions?

Catalyst referred Audience and Consumer Affairs to three trials which showed no mortality benefit from diets with lower saturated fats under the trial conditions. Two of these studies – MRFIT and WHI – were referred to in the program as *'ambitious trials, costing over $250 million, involving hundreds of*

thousands of patients [which] both failed to prove that lowering saturated fat could lower your risk of dying from heart attack':

- **Multiple Risk Factor Intervention Trial (MRFIT)**: According to the 1982 journal article, 'Multiple Risk Factor Intervention Trial: Risk Factor Changes and Mortality Rates',[17] this was a '*randomized primary prevention trial to test the effect of a multifactor intervention program on mortality from coronary heart disease (CHD) in 12,866 high-risk men aged 35 to 57 years*' which included interventions to reduce saturated fat intake and increase polyunsaturated fat intake. After an average of seven years follow up, the researchers found that '*risk factor levels declined in both groups, but to a greater degree for the [special intervention] men*'. Although the 7.1% difference in coronary heart disease mortality rates between the two groups favoured the intervention group, the difference was statistically non-significant. Furthermore, for all cause mortality, there was in fact a 2.1% higher death rate for the special intervention men (265 deaths) than the control men (260 deaths), but again the difference was not statistically significant.

- **Women's Health Initiative Trial (WHI)**: According to the 2006 journal article, 'Low Fat Dietary Pattern and Risk of Cardiovascular Disease: The Women's Health Initiative Randomized Control Dietary Modification Trial',[18] this randomized control trial of 48,835 postmenopausal women aged between 50 and 79 years concluded that '*[o]ver a mean of 8.1 years, a dietary intervention that reduced total fat intake and increased intakes of vegetables, fruits, and grains did not significantly reduce the risk of [coronary heart disease], stroke, or [cardiovascular disease] in postmenopausal women and achieved only modest effects on [cardiovascular disease] risk factors*.' These results occurred notwithstanding a significant reduction in LDL cholesterol levels in the intervention group.

- **Minnesota Coronary Survey Study:** According to the 1989 journal article, 'Test of Effect of Lipid Lowering by Diet on Cardiovascular Risk',[19] this double-blind, randomized clinical trial of 4,393 institutionalised men and 4664 institutionalised women '*compared the effects of a 39% fat control diet (18% saturated fat, 5% polyunsaturated fat, 16% monounsaturated fat, 446 mg dietary cholesterol per day) with a 38% fat treatment diet (9% saturated fat, 15% polyunsaturated fat, 14% monounsaturated fat, 166 mg cholesterol per day) on serum cholesterol levels and the incidence of myocardial infarctions, sudden deaths, and all cause mortality.'* Subjects remained on their diets for an average of 384 days. While serum cholesterol was reduced in the treatment group, '*[f]or the entire study population, no differences between the treatment and control groups were observed for cardiovascular events, cardiovascular deaths or total mortality*', although a favourable trend occurred in some younger age groups.

Each of these studies reduced saturated fat levels and none resulted in significant mortality benefits for participants. However, unlike the MRFIT and MCSS studies which involved decreases in saturated fat intake and increases in polyunsaturated fat intake, the WHI study intervention was a low fat diet. The focus on reduced fat intake saw women in the intervention group reduce their intake of saturated,

[17] http://jama.jamanetwork.com/article.aspx?articleid=377969.
[18] http://jama.jamanetwork.com/article.aspx?articleid=202339.
[19] http://atvb.ahajournals.org/content/9/1/129.long.

monounsaturated and polyunsaturated fat. The authors of the WHI study cautioned that it was *'not a test of the dietary guidelines currently recommended for prevention of CVD that specify … [inter alia] … replacement of saturated and trans fat with monounsaturated and polyunsaturated fat …'.* We are nonetheless satisfied that it was not materially misleading or inaccurate for the program to identify the WHI study as having failed to prove that lowering saturated fat intake could lower the risk of dying from heart attack.

In addition to these three studies, Dr Demasi stated in the program, '*An extensive review of the literature showed that the data was highly inconsistent. In fact, there were many long-term studies that refute the idea that saturated fat raises cholesterol'.* This statement was accompanied by scrolling text referring to the following studies, for which the program has provided URL references as discussed below:

- **The Bogalusa Heart Study** – reference provided: http://www.ncbi.nlm.nih.gov/pubmed/623054 - This study examined food intake and eating patterns in children and looked for relationships with arteriosclerosis risk factors, including serum cholesterol. A 24-hour recall methodology was used to identify the composition of the children's diets. Overall, the study found a '*lack of relationship of diet to serum lipids'*, concluding that the dietary components failed to explain 96% of the variability in risk factors. However, when the children were grouped according to their serum cholesterol levels, children with middle and high levels of blood cholesterol showed significantly greater fat intakes than those with the lowest serum cholesterol levels. The researchers concluded: '*Food may well be one environmental determinant of risk factor levels, but its definite influence remains to be clarified'.*

- **The Tecumseh Study** – reference provided: http://www.ncbi.nlm.nih.gov/pubmed/998550 - This study examined daily nutritional intake and serum lipid levels. While the Tecumseh Study is a long-term study, this particular research does not appear to be a long-term investigation of diet and cholesterol. The researchers asked participants to provide detailed recall of all foods eaten over the previous 24-hours and looked for relationships between dietary intake and serum lipid levels. It concluded that '*[c]holesterol and triglyceride levels were unrelated to quality, quantity, or proportions of fat, carbohydrate or protein consumed in the 24-hour recall period'.* The researchers observed: '*The absence of correlation between dietary intake and lipid levels indicates that variations of dietary intake are less significant determinants of serum lipid levels among free-living individuals than would be anticipated from the findings of metabolic ward studies conducted under controlled conditions*'.

- **The Evans County Study** – reference provided: http://ajcn.nutrition.org/content/16/2/238.long - This 1965 study examined cholesterol levels of 26 pairs of white men matched for age and classified as having high or low cholesterol, assessing their nutritional intake by two dietary interviews some 6 months apart. It found no significant correlation of serum cholesterol with dietary components, but a highly significant inverse relationship between exercise and cholesterol.

- **The Israel Ischemic Heart Study** – reference provided: http://www.ncbi.nlm.nih.gov/pubmed/5365596 - This epidemiological study of 10,000 male Israeli civil servants looked at the association of serum cholesterol levels with possibly related variables, including diet. No significant association was identified between saturated fat intake

and variance in cholesterol levels. The researchers described the relationship between diet and cholesterol as '*trivial*', concluding that there was '*essentially no relationship between dietary elements and cholesterol*'. The researchers suggested one explanation might be that dietary changes correlate with cholesterol changes within individuals when all the non-dietary factors are held constant, but negligible correlation is observed between an individual's usual diet and blood cholesterol where there is great variation among individuals in non-dietary factors.

- **The Health Professionals Follow Up Study** – reference provided: http://www.ncbi.nlm.nih.gov/pubmed/8688759 - This long-term study following 43,757 US health professionals without heart disease or diabetes sought to examine the association between fat intake and the incidence of coronary heart disease in men of middle age and older. Information about nutritional intake was gathered by questionnaire initially and again after each two year period. After six years, the study concluded that the data collected *'do not support the strong association between intake of saturated fat and risk of coronary heart disease suggested by international comparisons. They are compatible, however, with the hypotheses that saturated fat and cholesterol intakes affect the risk of coronary heart disease as predicted by their effects on blood cholesterol concentration.'* The authors observed that while *'a firm conclusion regarding the role of dietary fats to risk of coronary heart disease is unwarranted ...a prudent approach for prevention of coronary disease consistent with the results of this study and other evidence is to recommend a reduced intake of saturated fat, cholesterol, and trans unsaturated fatty acids accompanied by an increased consumption of foods rich in fibre, including cereals, vegetables, and fruit*'.

- **The Western Electric Study** – reference provided: http://www.ncbi.nlm.nih.gov/pubmed/7442730 - This is a 20-year follow up study evaluating diet, serum cholesterol, and other variables in 1900 middle-aged men. The abstract indicates that the '*results support the conclusion that lipid composition of the diet affects serum cholesterol concentration and risk of coronary death in middle-aged American men*'.

- **The Japanese Living in Hawaii Study** – reference provided: http://aje.oxfordjournals.org/content/97/6/372.short - This study employed a 24-hour recall dietary interview with 9,744 men of Japanese heritage living in Japan, Hawaii and California. The authors found statistically significant '*consistent and positive relationships between serum cholesterol level and dietary intake of saturated fat, animal protein and dietary cholesterol'.* The findings were statistically significant in both Japan and Hawaii, but for subjects in San Francisco *'the variation was large and no definite trend could be observed because of the small number of subjects'.* The report also noted that '*the fact that the nutrients considered in this study account for a relatively small amount of variance in serum cholesterol levels emphasizes the importance of other, perhaps non-dietary, factors'.*

Not all of the studies listed on screen refute Dr Grenfell's statement that intake of saturated fats leads to an increase in blood cholesterol. The Western Electric Study states that dietary fat does affect cholesterol and risk of coronary death; and the Japanese Living in Hawaii Study found a consistent and positive relationship between saturated fat intake and cholesterol levels which reached significance for subjects in Japan and Hawaii. Furthermore, while both the Bogalusa and Tecumseh studies are themselves long-term studies, the specific research cited by *Catalyst* from

these studies do not constitute long-term investigations of diet and cholesterol. Considered as a group, however, the listed studies do support the presenter's statement that the data is '*highly inconsistent'* and do include long-term studies finding no link between intake of saturated fats and increase in blood cholesterol. Given the qualified introduction from the presenter, we are satisfied that material facts were presented accurately and in context.

Later in the program, the presenter also stated:

> ***DR MARYANNE DEMASI:*** *The most influential and respected investigation into the potential causes of heart disease was carried out here, in the town of Framingham, Massachusetts. It began in 1948 and is still going on today. It's the longest observational study of its kind, involving over 5,000 residents.... When researchers went to look at the data 30 years later, they found that, after a certain age, it didn't matter what your cholesterol level was.*

This is an accurate description of the results of the study.

As noted above, the program also included Dr Grenfell's statement that meta-analyses had shown that there was convincing evidence that intake of saturated fats leads to an increase in blood cholesterol. Of the three publications to which the National Heart Foundation referred the program, one – the Mensink study – was referred to in the program. This was the study which the National Heart Foundation had singled out in response to the program's request for evidence that saturated fat intake raises cholesterol.

Dr Demasi referred to the Mensink study in the program as *'[showing] only certain types of saturated fat could raise bad cholesterol, but it also raised good cholesterol'.* The strongest conclusions of this paper were that replacing trans fatty acids and saturated fats with polyunsaturated fats had the biggest positive impacts on blood cholesterol and heart disease risk, but (consistent with Dr Sullivan's comments in the program) replacing saturated fats with carbohydrates did not have a clear positive effect. The study does seem to us to support Dr Grenfell's statement that intake of saturated fats leads to increased blood cholesterol. However, as the program noted, the study suggests a more complex situation, finding for example that lauric acid (a saturated fat found in coconut oil) greatly increased total cholesterol, but much of its effect was on HDL cholesterol – the so-called 'good' cholesterol. In our view, it was reasonable for the program to point out that the results of the Mensink meta-analysis did not resolve questions about the role of dietary saturated fat in relation to cholesterol and heart disease.

The program has also advised us that its research had identified other meta-analyses which reached contrary conclusions. For example:

- Siri-Tarino et al.'s 2009 meta-analysis of prospective epidemiologic studies which '*showed that there is no significant evidence for concluding that dietary saturated fat is associated with an increased risk of CHD or CVD.*'[20]

- Elwood et al.'s 2004 analysis of 10 cohort studies which concluded that there was no convincing evidence that consumption of milk is associated with higher risk of heart disease or stroke.[21]

[20] http://ajcn.nutrition.org/content/early/2010/01/13/ajcn.2009.27725.abstract.
[21] http://www.nature.com/ejcn/journal/v58/n5/abs/1601869a.html.

Taking into account the preponderance of sceptical commentary from both interviewees and the presenter, the program clearly favoured the perspective that claims that dietary saturated fats causes heart disease by raising cholesterol are unproven and exaggerated. In our view, it is fair to state that – overall – studies have failed to consistently and unequivocally show a clear causal link between intake of dietary saturated fat, elevated serum cholesterol and heart disease. Indeed, a great many of the research papers reviewed as part of this investigation identify this as one of their prime motivations. For example, the Mozaffarian et al. study to which the National Heart Foundation referred the program states:

> '*Reduction in saturated fatty acids (SFA) consumption is traditionally a major focus of dietary recommendations to reduce coronary heart disease risk (CHD). However, effects of such a strategy on clinical CHD events are surprisingly poorly established in both randomized controlled trials (RCTs) and prospective cohort studies*'.[22]

In stronger terms, the United Nation's Food and Agriculture Organisation 2008 Food and Nutrition Paper, 'Fats and fatty acids in human nutrition: Report of an expert consultation' stated:

> *'Few within-population studies have been able to demonstrate consistent associations between CHD risk and any specific dietary lipids, with the exception of trans fats and n-3 fatty acids. The available evidence from cohort studies and randomized controlled trials on which to make judgement and substantiate the effects of dietary fat on risk of coronary heart disease is unsatisfactory and unreliable."*[23]

ABC programs have an important role to play in challenging orthodoxies, sceptically examining data and drawing evidence based conclusions. There was nothing inappropriate in *Catalyst* subjecting the diet-heart hypothesis to rigorous scrutiny.

The ABC's impartiality standards are not intended to stifle reporting of alternate or unorthodox theories. Here, the program had clearly signalled to viewers that it would challenge the medical orthodoxy. The program examined the scientific evidence supporting the diet-heart hypothesis and, in our view, sufficiently demonstrated that the science supporting this hypothesis was not definitive and that there remains persistent and genuine scientific debate about the roles of diet and cholesterol in heart disease. The program established that there was room for alternative theories to be considered. It presented an alternative 'inflammatory' theory favoured by some of its interviewees. This alternative was appropriately presented by the program as a theory, not a proven fact.

We are satisfied on the basis of our review that the program's scepticism towards the diet-heart hypothesis was not unjustified and its presentation of an alternative approach did not amount to an undue favouring of that approach.

Finally, several complainants have asserted that the 'American experts' were unduly favoured because they are Americans and because Dr Sinatra and Jonny Bowden, in particular, have unorthodox and unscientific views.

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[22] http://www.ncbi.nlm.nih.gov/pubmed/20351774
[23] http://foris.fao.org/preview/25553-0ece4cb94ac52f9a25af77ca5cfba7a8c.pdf, p 129.

Catalyst notes that despite holding these views, they are a properly qualified medical practitioner and nutritionist, respectively; they were not asked to comment on areas beyond their known expertise; and independent scientific evidence was checked to validate their statements. The fact that they are American is not relevant. The story was largely recorded in the USA for production reasons including the availability of talent.

Conclusion – No breach of section 4.5, no breach of 2.1

7 Misrepresentation of the 4S trial data – Part II – Code of Practice section 2.2

Complaint

"At 9 min and 56 seconds into the episode, Professor Beatrice Golomb says:

> *"Right now the evidence has not supported benefit to women, even if they have heart disease, in terms of mortality and all cause morbidity. It has not shown benefit to elderly, even if they have heart disease. In fact, in the 4S trial, there was a 12% increase in mortality in the women in that group who were assigned to statin rather than placebo."*

Catalyst then briefly shows the relevant table from the relevant paper. If you freeze the frame you can see that the 12% increase in all-cause mortality for women was not even close to statistical significance (relative risk 1.12, 95% confidence interval 0.65 to 1.93; only 52 of the 827 women died during the trial). The 95% confidence interval of 0.65 to 1.93 indicates that there simply weren't enough female deaths to conclude a mortality benefit from either statin or placebo (the lower confidence interval of 0.65 indicates that statins might actually reduce mortality by up to 35% for women). Hence, as a statistician I can confirm that Professor Golomb's statement regarding "a 12% increase in mortality in the women" would be regarded by any competent statistician/epidemiologist as deliberately misleading.

But it gets better; all 7 of the other relative risk shown in the same frame indicated highly statistically significant protective effects for the statin including for deaths among the "elderly" (ie 60y) and for major coronary events among both women and the "elderly". Hence, I assert that Professor Golomb's statements regarding "the evidence has not supported benefit to women" and "It has not shown benefit to elderly" were more than misleading; they were brazen lies.... [and] Catalyst showed this table in a misleading context."

Professor Sullivan makes essentially the same complaint.

Transcript

> ***NARRATION:*** *Dr Golomb has scrutinised the data, and she's even more sceptical about the value of these drugs, especially in women.*
>
> ***Professor Beatrice Golomb:*** *Right now the evidence has not supported benefit to women, even if they have heart disease, in terms of mortality and all cause morbidity. It has not*

shown benefit to elderly, even if they have heart disease. In fact, in the 4S trial, there was a 12% increase in mortality in the women in that group who were assigned to statin rather than placebo. So the evidence really doesn't support that the benefit is the same for women and for men. And on top of that, women are at higher risk of complications from statins.

Assessment

This portion of the program conveyed Professor Golomb's views about the benefits of statins for women and the elderly. In our view, Professor Golomb was speaking generally about her review of the data in this area. Her comments were not confined specifically to the 4S study, although she did refer directly to this study to provide support for her views about mortality outcomes for women. In terms of compliance with editorial standards, the issue is whether the program made reasonable efforts to ensure that the material facts were presented accurately, and whether factual material was presented in a way that would materially mislead the audience.

Professor Golomb's comments drew from on her own (co-authored) review of the literature, 'Statins and Mortality', published in the insurance journal, *On the Risk.*[24] Amongst the conclusions of this literature review were the following relevant points:

'*Women, even those with heart disease or at high risk of it, have not experienced benefit exceeding harm as indexed by all-cause mortality in existing major clinical trials. Thus, the 4S and LIPID trials – which enrolled mostly middle-aged high risk patients with diagnosed coronary artery disease, showed significant benefits to all-cause mortality in the total sample … For women within these studies, however, the trends were approximately neutral (RR 0.95 for LIPID) or minimally unfavourable (RR 1.12 for 4S, 95% CI 0.65-1.93).*'[25]

And:

'Elderly (over age 70), even those with or at high risk of heart disease, have not experienced benefit exceeding harm as indexed by all-cause mortality, at least according to the sole randomized trial to focus on this group, the PROSPER trial. All-cause mortality with statin v placebo was neutral (RR 1.0). Incidentally, all-cause morbidity was neutral as well (RR 1.0).'[26]

Professor Golomb conducts research into statins and is a Professor of Medicine at the University of California. In our view, it was reasonable for the program to present Professor Golomb's assessment of the evidence, given her experience and expertise in this field.

In relation to women, we note that Professor Golomb qualified her statement somewhat in response to a further question:

***Dr Maryanne Demasi**: Should women take cholesterol-lowering medication?*

***Professor Beatrice Golomb:** In general, no. Now there may be exceptions. Medicine actually does have an element of art. And if women are from a family with severe familial*

[24] Vol. 25 n. 2 (2009), p 66-71.
[25] P 67.
[26] P 68.

hyperlipidaemia, where a lot of people are dying from heart disease in their 30s and 40s, that's a group where I would say there is an art.

In relation to the 4S study, the program has explained that it was aware that the 12% increase in mortality for women in the statin group did not reach statistical significance, but have explained that the point was that the study did not even show a trend in a favourable direction for women in the experimental group. While the 12% increase was not statistically significant and arguably should not have been included, the data quoted does support the main point of the grab, which was that the study showed no benefit to women in terms of mortality and morbidity.

In relation to the elderly, the term is inherently imprecise. As the complainants note, the screen shot featuring the results from the 4S study did suggest a mortality and morbidity benefit for patients aged over 60 years. The paper co-authored by Professor Golomb on which she bases her comments defines elderly as over age 70. In our view, the program's reliance on Professor Golomb and her published work constituted reasonable efforts; viewers would have understood the use of the term 'elderly' as signalling a certain imprecision, and would not have been materially misled by the material conveyed.

Conclusion – No breach of section 2.1 or 2.2

8 Merck Sharp & Dohme (MSD) – Part II – Code of Practice section 2.1

Did the program incorrectly state that it had sought comment from Merck Sharp & Dohme?

Complaint

Catalyst reported that it sought comment from MSD. MSD says that no contact was made.

Assessment

Catalyst has provided emails demonstrating that it approached MSD for responses to a number of detailed questions. MSD replied that it would not comment on the specific questions and stated only that:

'MSD is committed to ethical research and abides by the principals of good clinical practices. All clinical trials and their protocols undergo review by hospital ethics committees.'

We are satisfied that *Catalyst* contacted MSD for comment and they declined to provide specific responses to allegations.

Conclusion – No breach of section 2.1.

9 Unfair characterisation of Australia's medicines industry – Part II – Code of Practice sections 2.1 & 4.5

Complaint

Medicines Australia & Merck Sharp & Dohme (MSD) have complained that:

> *'The pharmaceutical industry was accused of 'criminal' conduct akin to 'organised crime'. Medicines Australia strongly rejects such accusation and feels that it is unfair (sic) characterisation of Australia's medicines industry.'*

They go on to note that Australia has a rigorous system for the approval of drugs.

Transcript

> ***Dr John Abramson**: Are the trials lying? No. I just don't think they ask the right questions. Why don't they ask the right questions? It's not in the interest of the drug companies to ask the right questions. So, it's creating the impression that the drugs are safe.*
>
> ***NARRATION**: Another complication with clinical trials is that drug companies don't recruit volunteers that reflect the typical patient on statins.*
>
> ***Dr Robert Grenfell**: The problem with the study design is that we exclude people with chronic disease or other co-morbidities. We exclude people who are very old or very young, and we'll certainly exclude people with other types of risk factors or diseases that may interfere with the metabolism of the drug. So we often get a skewed picture of what the side effect profile is.*
>
> ***Professor Beatrice Golomb**: The fraction of people with problems in my sort of real-world, on-multiple-medications, etc clinic is far higher. And I would say that in that sample it really seems in the order of a third of patients that develop problems.*
>
> ***Professor Rita Redberg**: There are a lot of ways that one can manipulate data in a trial. Trials do what they call a washout period, and what that means is before they choose the people that are going to be in the trial, they give everybody the drug, and the people that have side effects get excluded from the trial. And they say that so people aren't uncomfortable when they are in the trial. But of course it takes out all the people that have side effects, and that's very commonly done in drug trials.*
>
> ***Dr Maryanne Demasi**: So the side effects would be grossly underestimated.*
>
> ***Professor Rita Redberg**: Yes, it would definitely grossly underestimate the number of people that have side effects. They're not as safe as they're made out to be, no.*
>
> ***Professor Beatrice Golomb**: In its effect, it's certainly scientific fraud, and in its effect it's organised crime. It's always difficult to allege intent, but it is clear that manipulation of evidence subjects many people to treatments that those people should never have been subjected to.*
>
> ***Dr John Abramson**: I think there is criminal activity that goes on. And I think when drug companies act in ways that misrepresent information that leads to harm, they ought to be held*

responsible, just like any other individual or organisation that conducts itself in a way that leads to harming other people.

***NARRATION**: Drug companies have a history of illegal activity. This is just a sample of the billions of dollars in fines they incur for things like fraud and bribery in any given year. In the '80s, when President Reagan came into office and slashed funding to the national institutes of health, it left a gaping hole for private industry to move in. Nowadays, around 85% of trials are funded by drug companies. A review concluded that if a drug company paid for a trial, it was 24% more likely to report the drug was effective and 87% less likely to report the drug's side effects.*

***Dr John Abramson**: There is a sense that science is science, so it doesn't matter who pays for it. And yet because the research is privatised, the fundamental purpose for which it's conducted has changed. It's not to improve the public's health - it's to fulfil the fiduciary obligations of the sponsors and create an opportunity to maximise profits instead of improve the public's health.*

***Dr Maryanne Demasi**: Some might say that that's a rather cynical view of how science works.*

***Dr John Abramson**: To say it's cynical that commercial sponsorship of science taints the science is just totally naive. It's silly. Business is in business. Their job is to make money. We ought to be clear in our public discourse that to say we've got a bias in commercially sponsored research is neither cynical, nor paranoid, nor impolite - it's a fact. So let's just accept it as a fact and stop being naive at our own expense.*

Assessment

The program did not mention and was not concerned with the procedures for approving drugs in Australia. There was no suggestion that any of the drugs mentioned were unsafe to the extent that they should not have been approved for use by Australian authorities. Therefore, it was reasonable not to detail the Australian regulatory regime.

None of the factual statements in the section dealing with the drug companies has been disputed. The statement that '*drug companies have a history of illegal activity*' was in the context of a discussion with an American academic and viewers would not have understood it as referring to Australian companies.

In any event, there is a history of criminal convictions of many pharmaceutical companies, including the parents of some of the companies mentioned on the program. See:

http://www.independent.co.uk/life-style/health-and-families/health-news/drug-giants-fined-11bn-for-criminal-wrongdoing-8157483.html;

http://www.fda.gov/ICECI/CriminalInvestigations/ucm301329.htm; &

http://www.bloomberg.com/apps/news?pid=newsarchive&sid=a4yV1nYxCGoA.

Other comments by, for instance, Dr Abramson were opinion. *Catalyst* has explained that Medicines Australia was approached for comment and the program was told to approach the drug companies

directly for a right of reply. MSD, Pfizer and AstraZeneca were all approached for comment, the former two declined and AstraZeneca's denial of the claims made was included in the program.

Audience and Consumer Affairs are satisfied that this segment was accurate and the program, did not unduly favour the perspective of the critics of the industry.

Conclusion – No breach of section 2.1 or 4.5.

10. Failure to provide material context by not disclosing the commercial interests of some of the experts featured – Parts I & II – Code of Practice section 2.2

Complaint

Several complainants argue that Dr Jonny Bowden, Dr Michael Eades, Gary Taubes, Dr Ernest Curtis and Dr Stephen Sinatra have businesses promoting nutrition based products, diets, books and supplements that constitute conflicts of interest which should have been disclosed to viewers.

A similar argument is made in relation to Dr Abramson because he gives paid expert evidence n litigation against drug companies.

Complainants allege that by failing to report these potential conflicts viewers were misled. The information provides viewers with important context to help them assess the credibility of the interviewees.

Assessment

Both Dr Jonny Bowden and Dr Ernest Curtis feature prominently in the two episodes of *The Heart of the Matter,* while Dr Stephen Sinatra and Dr Michael Eades appear prominently in the first episode. The program explains that these '*medical experts*' challenge the mainstream '*medical paradigm*' that cholesterol and saturated fat cause heart disease.

The program describes Dr Jonny Bowden as a '*California-based nutritionist*'; Dr Michael Eades as a '*physician*'; Dr Ernest Curtis as a '*cardiologist'* and Dr Stephen Sinatra as a '*cardiologist*'.

Comments challenging mainstream medicine were also included from Gary Taubes who was introduced as a '*science writer*' and Dr John Abramson who was described as: *'Harvard Doctor John Abramson ... an expert in litigation involving drug companies. He says we're not being told the whole truth about the dangers of these drugs.'*

Catalyst has argued that '*Everyone interviewed had a conflict of interest including Ass Prof David Sullivan who is a member of several advisory panels within the pharmaceutical industry. In addition, Dr Sullivan's research is funded by the National Heart Foundation.*'

The issue is whether particular information about the commercial interests of the interviewees was material context, and necessary to assist viewers to make up their own minds about the issues being discussed in the program and the credibility of the experts featured. It is important to ensure viewers are not likely to be materially misled about a person's qualifications by omission of information.

It is the case that Gary Taubes' interests in the subject at hand would be obvious to the viewer; he was introduced as a '*science writer*' and it would therefore be self evident that he would earn an income from science journalism. Similarly, Dr John Abramson's interests were made clear; he was described as '*an expert in litigation involving drug companies*' and he disclosed in the program that he spends *'a lot of time as an expert in pharmaceutical litigation'*.

Dr Sinatra, Dr Eades and Dr Bowden all directly benefit from the promotion of their views through the sale of supplements, books and videos. Each of these interviewees has a personal website which sells a variety of products which are directly relevant to the subject at hand. Both Dr Bowden and Dr Sinatra endorse and sell supplements for 'heart health'. Further, Dr Bowden and Sinatra co-wrote 'The Great Cholesterol Myth' with a foreword by Dr Eades, and each of their personal websites sell books and DVDs providing health and nutrition advice based on the premise that cholesterol does not cause heart disease. These represent direct commercial interests in a particular point of view which were not specifically disclosed in the program.

Catalyst argue that interviewees representing both sides of the argument for and against the use of statins were conflicted, and that had all those conflicts of interest been disclosed this would not have materially influenced the viewer's opinion.

The program has provided references demonstrating that Associate Professor David R Sullivan has served on advisory panels within the pharmaceutical industry including Pfizer Australia, AstraZeneca, Merck Sharp and Dohme and Schering Plough – http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1904423/; he has also received research grants from AstraZeneca, Eli Lilly, Merck Sharpe and Dohme, AMGEN and Sanofi Aventis – http://ajconline.org/article/S0002-9149(08)01388-X/fulltext and http://jaha.ahajournals.org/content/2/5/e000360.full. Some of these companies are leading manufacturers of statins; this conflict of interest was not disclosed in the program.

With regard to Dr Robert Grenfell, *Catalyst* argue that as a Director of the National Heart Foundation, he represents the views of a medical authority which receives significant amounts of money each year from industry and pharmaceutical companies. It is the case that food companies pay a licence fee to gain a 'tick' of approval once their product has met the NHF standards – http://www.heartfoundation.org.au/SiteCollectionDocuments/NHF-Annual-Report-2011.pdf. Further, the National Heart Foundation has received millions of dollars from pharmaceutical companies for research, scholarships and fellowships via a scheme called the Pharmaceutical Roundtable – http://www.heartfoundation.org.au/information-for-professionals/pharmaceutical-roundtable/Pages/default.aspx.

The program also makes the point that conflicts of interest are not disclosed as a matter of course:

'...Catalyst, as a magazine style popular science program, often features stories with experts that have outside interests (often commercial) and it is not a matter of course to declare the outside interests of all experts. It's impractical and out-of-step with the established format to do so, and typically the outside interests aren't relevant to an audience's understanding of the viewpoints expressed by each expert or their credibility ... noted scientists like Sir Gustav Nossal, Tim Flannery, and inventor of the Gardasil vaccine Prof Ian Frazer (who earns millions from sales and distribution) are all referred to as experts in their field rather than their outside interests.'

There is no suggestion that the views of the interviewees featured are not sincerely held simply because of their various commercial interests. However, Audience and Consumer Affairs accept that both sides of the argument regarding the use of statins and the role of saturated fats in heart disease are to some degree conflicted. We are satisfied that there was no material qualitative difference between the conflicts of interest of those interviewed in the program; therefore a roll call of the potential and actual conflicts of each of the interviewees would not have represented essential context for the audience. Rather, it would have appeared incongruous within the usual format and approach of the program.

Further, it is likely that the audience would recognise that the experts featured represent committed and to a large degree fixed positions in the debate; and that they would make their living, one way or another, by representing that position.

Conclusion – No breach of section 2.2.

11. <u>Failure to provide material context in relation to use of statins and undue favouring of view that statins do more harm than good – Part II – Code of Practice 2.2, 4.5 and 7.6</u>

Did the program unduly favour an anti-statin viewpoint in its presentation of the evidence for the benefits and harms of statins?

Complaint

Complainants allege that Part II:

- Did not differentiate between primary and secondary prevention and glossed over the fact that statins are proven to be life saving among those who have had heart attacks.
- Ignored evidence of the benefits of statins for prevention of heart disease in primary care of 'high risk' patients.
- Failed to provide information on the reduction of CVD in Australia due to various factors including the use of statins.

For instance:

'I do not believe that the program presented a balanced view of the debate concerning diet, the role of cholesterol and statins. I had provided extensive evidence-based arguments over

the preceding months to try to address the serious misconceptions that were promoted in both episodes' (Prof Sullivan).

'The Heart Foundation believes critical information was missing in the debate, particularly around the effectiveness of statins' (Dr Roberts, CEO National Heart Foundation)

Assessment

Distinction between primary and secondary prevention

The program commenced using a series of short grabs, interspersed with narration, introducing the key themes that would be addressed in the program: that the benefits of cholesterol lowering drugs had been seriously exaggerated and that drug companies distort research results to overplay the drugs' effectiveness and downplay adverse effects.

The narrator's introductory comment that there is now evidence that the majority of people prescribed cholesterol-lowering drugs won't benefit was followed immediately by Professor Rita Redberg saying '*None of these people are less likely to die'*. This statement is not accurate for patients in secondary prevention.

Later in the program, the narrator stated that 30 years after the drugs were introduced, '*many are concerned that the benefits of these drugs have been grossly exaggerated'.* Professor Rita Redberg was introduced as a '*world-renowned cardiologist*' who believes that *'barring a genetic condition, the only people who live longer by taking a statin are those that have already had a heart attack or stroke'.* Professor Redberg expressed the view that only a very small number of patients in this group would benefit from taking a statin. The narrator then stated: '*But this hasn't limited their use. These drugs are now widely prescribed to relatively healthy people – those without diagnosed heart disease. And Dr Redberg warns most of them won't benefit'.* After some further discussion of views about the benefits of treating primary care patients with statins, Professor Redberg's earlier grab – '*None of those people are less likely to die'* – was featured, clarifying that this statement referred to primary care patients, not all patients prescribed statins. The narrator then stated: '*Unless you've already been diagnosed with heart disease, then taking a statin won't help you live longer'.*

The introduction to the program used Professor Redberg's grab about patients in primary care without the necessary context in which it appears later in the episode. However, viewers would be unlikely to place significant weight on the opening statements, understanding that these frames provide only a general indication of the main themes that would be explored in the program itself. Sufficient information was provided in the body of the program to allow viewers to understand that a distinction was being drawn between statin use for patients already diagnosed with cardiovascular disease (secondary prevention), and those who had risk factors but who had not been diagnosed with cardiovascular disease (primary prevention).

It is apparent that the program made efforts to distinguish between the two classes of statin patients. Comments from Professor Redberg differentiated between the two people in one hundred in the secondary care group who would benefit from taking a statin, and '*healthy people'* for whom *'the data is not there to suggest that those people are better off taking a statin'.*

Statin use in secondary prevention

According to the Ray et al. meta-analysis provided to us by *Catalyst, '[t]here is little debate that, compared with placebo, statin therapy among individuals with established coronary heart disease (CHD) not only prevents complications related to atherosclerosis but also reduces all-cause mortality*'.[27] In support, Ray et al. cite the 4S study (*Lancet,* 1994), the LIPID study (*New England Journal of Medicine,* 1998) and the Heart Protection Study Collaborative Group MRC/BHF Heart Protection Study (*Lancet,* 2002). Similarly, the National Heart Foundation's summary of its recommendations for cholesterol management state: '*After a heart attack, treatment with a statin is first-line, evidence-based management. Some of the largest studies ever conducted in medicine have demonstrated that statins decrease further heart attacks and save lives'.*[28]

The program dealt with the use of statins in secondary care via narration and a grab from Professor Redberg:

> ***NARRATION:*** *It's been about 30 years since statins were first introduced as the new blockbuster drug in heart disease. And millions of people around the world are being prescribed these medications. But many are concerned that the benefits of these drugs have been grossly exaggerated. Professor Rita Redberg is a world-renowned cardiologist. She says, barring a genetic condition, the only people who live longer by taking a statin are those that have already had a heart attack or stroke.*
>
> *Nat sot*
>
> ***NARRATION:*** *And of them, only a very small number will benefit.*
>
> ***Professor Rita Redberg****: One or two people in a hundred will benefit from taking a statin. What people don't understand is that means the other 98 will get no benefit at all. It's not going to reduce their chance of dying.*

Expressing the reduction as two in a hundred patients is consistent with how these results are often described in the scientific literature. The program has advised that this figure was sourced from The NNT.com (Number Needed to Treat). The accuracy of the NNT figures has not been called into question in any of the complaints received by the ABC. We nonetheless compared the NNT figures with those cited by others. For example:

- Thompson and Temple[29] provide figures for all cause mortality in the following trials:

Trial	**Absolute % reduction**	**Number needed to treat**
4S	3.3%	30
CARE I	< 1%	100

[27] http://www.abc.net.au/catalyst/heartofthematter/download/RayKKprimaryprevention.pdf.
[28] http://www.heartfoundation.org.au/SiteCollectionDocuments/Heart%20Foundation%20summary%20of%20recommendations%20for%20cholesterol%20management%20-%20Catalyst%20-%20FINAL.pdf.
[29] http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1079612/.

LIPID	3.1%	32
Heart Protection Study (14% of patients in secondary prevention)	1.8%	56

- Hurley[30] gives the following figures for all cause mortality in three trials:

Trial	**Absolute % reduction**	**Number needed to treat**
4S	3.5%	29
CARE	0.8%	125
LIPID	3.0%	33

These calculations suggest that somewhere between 1 and 4 of every 100 people taking a statin in secondary prevention will experience a mortality benefit. They are not so strikingly dissimilar to the figures cited by Professor Redberg to suggest that those figures are unreliable.

While the figure of two in a hundred secondary care patients receiving a mortality benefit is consistent with the NNT.com figures, suggesting that *'the other 98 will get no benefit at all'* is not strictly accurate, since it does not allow for non-mortality benefits such as reductions in heart attacks and strokes. According to The NNT.com, for those in secondary prevention who take statins for more than 5 years, one in 83 will have their life saved (1.2%), one in 39 will be helped to prevent a non-fatal heart attack (2.6%), and one in 125 will be helped through prevention of stroke (0.8%); however, one in 50 will develop diabetes (2%) and one in 10 will experience muscle damage (10%).

Catalyst has explained that Professor Redberg's reference to '*no benefit at all'* is an accurate assessment of the aggregate benefits of statins; that is, the actual likely outcome for the patient once the benefits and adverse effects have been taken into account. They also point out that Professor Redberg immediately added further context, specifying '*It's not going to reduce their chance of dying'. Catalyst* argue that *'the aggregate of benefits of statins in secondary prevention applies only to mortality. The reduction in heart attack and stroke are far outweighed by other harms of the drug which – more importantly – are severely under reported in clinical trials'.* We are not persuaded that this reliance on 'net benefit' was made sufficiently clear to viewers of the program.

The rushes available on the program website[31] indicate that other interviewees were considerably more positive about the use of statins in secondary care and were concerned that these drugs, which they considered life-saving, were underutilised amongst this group. For example, Dr Grenfell from the National Heart Foundation stated:

[30] http://www.australianprescriber.com/magazine/22/5/114/7.
[31] http://www.abc.net.au/catalyst/heartofthematter/.

'*… the hardest part in the Australian context is that most people who have had a heart attack who need to be on this medication are not taking it*.'

And

'… we're looking at a reduction one in five … reducing the heart attack rate by treating people in a secondary prevention model … I've had a heart attack and I'm participating in secondary prevention … I will reduce my chance of a heart attack quite substantially – a 1 in 5 chance. Because if I don't do that the other studies show that 1 in 3 will be back in hospital within 1 or 2 years with a significant cardiac event and of those with a significant cardiac event, a third of them will die. So that's what we're looking at preventing here.'

In its email to Dr Demasi, the National Heart Foundation also emphasised the reduction in percentage terms (using slightly different figures):

- *Major coronary events reduced by one fifth (21%) (defined as coronary death, non-fatal MI, coronary revascularisation, or stroke)*
- *Death from any-cause is reduced by 10%*
- *1 in 5 coronary deaths are prevented (i.e. 20% reduction).*[32]

This material was not included in the broadcast story.

In a section of his interview, Professor Sullivan pointed out to Dr Demasi that a 2% reduction in mortality for a treatment group translates to a 30% reduction in mortality relative to all of the participants in the trial. He expressed the view that *'An absolute reduction of 2 or 3% is really a very substantial improvement'.*

This material was not included in the broadcast story.

In response to criticisms of this aspect of the program, *Catalyst* has expressed the view that it did not dismiss the effect of statins:

'For secondary prevention patients treated with a statin … we DO state in the program that statins are able to delay deaths. However, these numbers are rather modest in the opinion of Professor Redberg. Only 2 in 100 people treated with a statin in secondary prevention will live longer. That means the other 98 people will not live any longer. These figures are derived from a combination of the secondary prevention statin trials and can be referenced on TheNNT.com website … Overall Sullivan and the Heart Foundation AND Redberg all give statins to people in secondary prevention … '.

The program focussed predominantly on the mortality benefits of statins, rather than the benefits they have been found to have in prevention of further heart attacks and strokes. This was a deliberate decision as the program wanted to be clear about the extent to which statins do actually save lives, information which it believed had received inadequate attention amongst the 'hype' associated with statins. In particular, the program took the position that it would avoid 'relative risk'

[32] The NHF cites the most recent Cholesterol Treatment Trialists' Collaboration meta-analysis as the source of these figures, www.ncbi.nlm.nih.gov/pubmed/21067804.

statistics in favour of absolute percentages because it considered this to be '*the most honest way of reporting to a lay audience whether the risk of mortality is high or low'.* The program explains:

> *'If you are told that you have a 2 in 100 chance of living longer if you take a drug, we think any reasonable person would conclude that the probability of living longer with the drug is low given they have a 98% chance of NOT living longer. If you say that a drug reduces a person's risk by a relative risk of 50%, then it's deceptive because the actual or absolute risk went from 2% down to 1%'.*

In our view, there was nothing inappropriate in the position that the program adopted in relation to absolute and relative risk statistics. However, there was nothing to prevent the program from incorporating absolute risk statistics to express the effectiveness of statins for the secondary prevention group. As indicated above, these figures were available from the NNT.com website that the program had otherwise relied upon. The effect of failing to include this information, combined with the program's emphasis on the adverse effects associated with statin use, was that the program failed to provide a principal relevant perspective about the benefits of statins in secondary prevention.

In effect, there were two contrasting viewpoints expressed by Dr Grenfell and Dr Sullivan that were not included in the broadcast program: the perspective that statins were not reaching enough patients in secondary prevention; and the perspective that statins offered considerable benefits to patients in secondary prevention. These perspectives could be described as 'orthodox' in the broader debate around statin use. They are important perspectives for an understanding of why statins are prescribed in such large numbers, and whether their use is appropriately targeted. These two themes were part of the overall message of the program – that statins are overprescribed and their benefits exaggerated.

The effect of omitting these perspectives was that the program presented the data in a manner that minimised rather than emphasised the benefits of statins in secondary care.

The material that we have reviewed during this investigation gives us confidence that this was not done deliberately in order to mislead the audience, but rather because it suited the overall focus of the story. The program has explained that the points made about statin use in secondary prevention were not considered an important point to make in the context of a story that was primarily concerning the use of statins in primary care.

We accept that in a story examining an unorthodox theory it would normally be enough to state the agreed facts briefly while spending most time examining the alternative hypothesis. However, having raised the issue of statins in secondary prevention, the program was obliged to deal with that issue accurately, impartially and mindful of the need to mitigate risk.

In our view, the approach adopted by the program was problematic. The information that was presented was mostly accurate, but a key perspective about the full benefit of statins in secondary prevention was missing. Airing this perspective was particularly important given the emphasis in the program on the adverse effects of statins. Its omission meant that viewers were not given sufficient, clear information to allow them to properly weigh the benefits of statins in secondary prevention.

Statin use in primary prevention

The use of statins in primary care is highly contentious and was an important issue addressed in Part II.

Most studies distinguish between primary and secondary care but do not distinguish among different groups within the primary care category.

The situation is further complicated by the fact that studies sometimes assess the benefits in terms of mortality outcomes, while others do not.

Catalyst focussed on the measure of mortality in its analysis, which was revealed in both the interviews and in the narration. Reference was also made to the debate over the trade-off between morbidity benefits and side effects.

This assessment examines whether the program reflects the weight of evidence in relation to statins and primary care and whether it includes the principal relevant perspectives.

The case against the general use of statins in primary care is supported by a number of studies and meta-analyses. For example, The NNT.com concludes on the basis of its review of the evidence that statin drugs given for 5 years for heart disease prevention (to patients with no known history of heart disease) will not help prevent any deaths.[33] The NNT.com nonetheless acknowledges that controversy exists about whether mortality is reduced by statin use in this group and that others interpret the data differently. The program placed significant weight on the NNT.com conclusion, judging it to provide the most independent view of the available evidence.

On the other hand, the case for statin use in primary prevention is made in studies such as the 2013 Cochrane study,[34] the 2012 CTT analysis,[35] and the 2009 Brugts et al. analysis.[36] While there are critics of these studies and analyses, they have been influential. The National Heart Foundation cites Brugts et al. and earlier analyses by the Cochrane Heart Group and the CTT to support its conclusion that '*[t]he use of stains as first line lipid-lowering therapy for the management of absolute cardiovascular disease risk is at the highest evidence level (Grade A)'*.[37]

Amongst those who see value in statin use in primary prevention, there exist a range of views about how they should be used. One viewpoint – favoured by the National Heart Foundation – is that the evidence does not support a mortality benefit for the general use of statins in primary care. For example, the National Heart Foundation's Dr Grenfell clearly stated in interviews that he believes statins are overprescribed for patients at low and moderate risk and the Foundation's published guidelines reflect this position.

[33] http://www.thennt.com/nnt/statins-for-heart-disease-prevention-without-prior-heart-disease/.
[34] http://www.ncbi.nlm.nih.gov/pubmed/23440795.
[35] http://www.abc.net.au/catalyst/heartofthematter/download/CTTstatinsforover50s.pdf.
[36] http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2714690/.
[37] http://www.heartfoundation.org.au/SiteCollectionDocuments/Heart%20Foundation%20summary%20of%20recommendations%20for%20cholesterol%20management%20-%20Catalyst%20-%20FINAL.pdf.

However, both Professor Sullivan and the National Heart Foundation consider that statins should be used in primary care of 'high risk' patients who have not been diagnosed with cardiovascular disease. The NHF defines 'high risk' in this context as patients having a greater than 15% risk of CVD within the next 5 years.[38]

Both Professor Sullivan and the National Heart Foundation take a multi-factorial approach to the treatment of risk for cardiovascular disease. As the National Heart Foundation guidelines state in their recommendations for management of primary prevention, *'Assessment of cardiovascular disease (CVD) risk on the basis of the combined effect of multiple risk factors (absolute CVD risk) is more accurate than the use of individual risk factors, because the cumulative effects of multiple risk factors may be additive or synergistic'*.[39] In their interviews, both Dr Grenfell and Professor Sullivan repeatedly emphasised the importance of this multi-factorial approach. For example, in parts of his interview which were not included in the broadcast program, Dr Grenfell's comments included:

- *'We've had this shift towards risk profile rather than just the single risk issue, so you could have a cholesterol level of 6.8 or 7.0 and still have a moderate or low cardiovascular risk. Whilst the guidelines – the old lipid guidelines – might have said yes, we would treat that, if your absolute risk level in fact is moderate or low, the answer would be do lifestyle intervention first and try to change it in that manner before, but continue to monitor'* (17:58).

- *'For levels lower than [7.5], we are … alarmed that people are reaching straight for the script pad because we should be looking at more of the interventions such as increasing physical activity, stopping smoking and doing some dietary change… in the first instance. That's what risk, or stratifying risk, is all about'* (19:13).

- *'High cholesterol on its own is not a good predictor of heart disease … If it's in the very high range … it is a much stronger risk of heart disease. But if it's in the ranges below 7.5, it's not necessarily a good, strong indicator. You need to take into account all the other risk factors of whether you'll have a heart attack or not'* (20:40).

- *'Cholesterol itself is still only a contributor to subsequent heart disease … You really need to look at all the other risk factors that are involved in the heart disease'* (25:44).

Similarly, Professor Sullivan's comments which were not included in the broadcast program included:

- *'I'd like to emphasise that the avoidance of what we call morbidity – nasty events like heart attacks or strokes which leave serious disabilities, which seriously impair quality of life. I think there is ample justification for seriously trying to treat risk factors. I think we'd have to*

[38] http://www.heartfoundation.org.au/SiteCollectionDocuments/Heart%20Foundation%20summary%20of%20recommendations%20for%20cholesterol%20management%20-%20Catalyst%20-%20FINAL.pdf.
[39] ibid

be very critical of an approach which did not treat risk factors. We're not just talking about cholesterol. We're talking about smoking, diabetes, everything else here' (33:03).

- Responding to Professor Redberg's view that risk factors should be treated but statins should not be prescribed, '*I think that's an inappropriate, selective approach which doesn't have any evidence to back it up'* (34:06).

- *'I think it's important to stress that cardiovascular disease is the result of multiple risk factors and that goes beyond cholesterol and includes things like diabetes and blood pressure. However, all of those issues really do require a dietary approach and where necessary a pharmaceutical approach … I think we can be very relieved for the fact that appropriate cholesterol interventions are very powerful in preventing cardiovascular disease. We need to get the most out of that because at the moment, we're probably only preventing about a third of the cardiovascular events that are available to be prevented'* (34.14).

In contrast, Professor Redberg is of the view that in most circumstances statins should not be prescribed to patients in primary prevention, even if they have a number of other risk factors. These views were presented in the program in the following manner:

> ***NARRATION:*** *These drugs are now being widely prescribed to relatively healthy people - those without diagnosed heart disease. And Dr Redberg warns most of them won't benefit.*
>
> ***Professor Rita Redberg:*** *For healthy people, even people that have a lot of risk factors. So they might have high blood pressure, they might smoke, they might have diabetes. The data is not there to suggest that those people are better off taking a statin. No, I don't think it's a wonder drug.*
>
> ***NARRATION:*** *But Dr David Sullivan disagrees. He says all the risk factors should be considered equally, including cholesterol.*
>
> ***Assoc Prof David Sullivan:*** *If you want to mount these arguments about not treating the cholesterol, you've got to take the responsibility of saying it's not necessary to treat these other risk factors either. I would certainly encourage people who are considering cessation of treatment for perceived side effects and so forth to discuss it with their doctor.*

While this segment did indicate that there was a difference of views about the use of statins in primary prevention, the grab included from Professor Sullivan did not adequately explain the perspective of those who favour targeted statin use in these patients. On the other hand, the views of those who do not favour use of statins in primary prevention were outlined in some detail in the narration and grabs from Professor Redberg, Dr Abrahamson and others.

As indicated above, amongst those who argue for statin use in primary prevention there appear to be at least two broad groups – those who advocate a wide-scale, general medication of (at least) the older population, and those who advocate for a targeted approach.

As we understand it, a key point made by the proponents of targeted statin use in primary prevention is that a select group of 'high risk' patients – that is, people with a greater than 15% risk of developing coronary vascular disease within 5 years – will benefit from taking statins. Those who hold this view also agree that there are a substantial number of people who receive statins in primary prevention unnecessarily, as they are in a 'low risk' category.

The program did not explain the 'stratified risk' approach favoured by the National Heart Foundation and others. In his interview with Dr Demasi, which was not included in the broadcast, Dr Grenfell said:

> *'In low risk patients, again, our recommendation is no medication at all... on the other side of that, by stratifying the general population to those in the high risk, we are only treating those that would get the greatest benefit from us for treating those'.*

However, the program did include the National Heart Foundation's view that statins are overprescribed:

> ***NARRATION:*** *The National Heart Foundation of Australia agrees that people are being prescribed statins unnecessarily.*
>
> ***Dr Robert Grenfell:*** *I would agree that there are people in Australia today who are being treated for cholesterol where their cardiovascular risk is not high. And you have to question whether they should in fact actually be on that.*

The program also drew attention to more extreme proposals, such as media reports suggesting that '*everyone over the age of 50 should be taking a statin to reduce their risk of heart disease*', a suggestion by a group of doctors that *'statins could counter the effects of eating a burger [and should] be handed out as free condiments, just like ketchup',* and *'that statins be put in the public water supply'.*

One of the strongest criticisms of the program has been that it has potentially caused harm by failing to address the perspective that statins are useful in primary prevention of patients considered to be at high risk of developing heart disease.

In response *Catalyst* writes:

> *'... this group of high risk patients without CV disease are a minor group. This is confirmed in the email attached. Dr Newman has done extensive peer reviewed assessments of the data on the benefits of statins. He is an independent reviewer of the literature and his analyses are corroborated by many other independent sources (like the Therapeutics Initiative). You will see the bits highlighted in yellow are confirmation that this 'subgroup' is small. Most importantly, this group would not alter the overall messages of the program. A 30 minute program (which was very clear in the opening) explored why experts believed the benefits of statins are exaggerated, the risks are underestimated and that the majority of people on*

statins do not benefit overall. We believed this broad message (which was clearly corroborated by the Heart Foundation in the interviews) was achieved successfully'.

Dr Newman writes:

'Our assessment is based on the average patient in the trials presented, and our interpretation is in line with many others....As for diabetes patients and others with a 'very high risk' profile, these are selected subgroups and they may benefit more than others. However this is speculative, and based largely on extraction of subgroups from trial data... Few trials were performed exclusively in diabetic patients, making this a post-hoc question. In contrast, a number of studies were done examining solely primary prevention or solely secondary prevention populations, making this distinction (the one we make) robust and non-speculative.

Moreover, it is accurate to say that very high risk primary prevention patients are a small minority of the overall cohorts in these studies, and in the population overall....Therefore at TheNNT, although risk profile consideration may prompt statin therapy for some, we do not consider these single-variable defined subgroups (diabetes, renal disease, etc.) to be reasons for statin treatment. The only single variable we find compelling is known CAD'.

Catalyst has also explained that the stratified risk approach was omitted because it is '*erroneous'* and lacks an evidential basis. However, the effect of excluding this issue was that viewers were not given the opportunity to hear both sides of the argument, and were not left in a position to make up their own minds.

While we accept that *Catalyst* made the decision not to include the 'targeted primary prevention' perspective in the program in good faith and in the interest of clarity and brevity, and its assessment of the weight of evidence, we nonetheless believe this was an error of judgement.

However contentious, it is a view that is very widely held by a large number of eminent physicians and medical bodies. While making the point that the National Heart Foundation still strongly supports the use of statins for this group may have complicated the story, the potential for harm is a significant factor. Notwithstanding criticisms of the methodology of some of the studies, the perspective is a significant strand of thought and cannot be dismissed.

It is a principal relevant perspective and the effect of its exclusion was to unduly favour the perspective that statins are ineffective in primary prevention.

Potential for harm

Given the high level of trust audiences have in the ABC, the large numbers of Australians being prescribed statins and the dominant message of the program that the benefits of statins had been exaggerated, there was the potential that the program could influence viewers not to take their prescribed statins.

The relevant editorial standards provides as follows:

7.6 Where there is editorial justification for content which may lead to dangerous imitation or exacerbate serious threats to individual or public health, safety or welfare, take appropriate steps to mitigate those risks, particularly by taking care with how content is expressed or presented.

In our view, there is no serious question that the program had ample editorial justification for presenting material which questioned the use of statins in both secondary and primary prevention. Over a number of years, the program makers had followed scientific debate about the efficacy and adverse effects of statins and they formed the legitimate view that this material should be brought to the attention of a wider audience with an interest in science. As ABC Television's flagship science program, it was appropriate for *Catalyst* to present this material. The purpose of this program was to generate debate about the use of statins. Since most key participants agreed that statins are overprescribed, that debate is clearly in the public interest.

It is somewhat more difficult to conceive of the program as '*exacerbating serious threats to individual or public health, safety or welfare'.* There is little guidance available to us to clarify what might amount to a serious threat. There is an inherent danger when any program presents criticisms of controversial medicines or medical procedures that information will be misconstrued and that people will act without consulting experts or fully considering the consequences. That is not a reason to avoid these controversial subjects if they are in the public interest.

In any case, the program clearly recognised the possibility that individuals might act rashly and mitigated this risk by including a voice over prior to and at the conclusion of the second episode advising that the views expressed in the program were not intended as medical advice and viewers should consult with their doctors regarding medications. The importance of seeking medical advice before discontinuing medication was also reiterated by Professor Sullivan in a grab that was included in the broadcast program.

We are satisfied that these steps were appropriate and adequate and the program did not breach 7.6.

Conclusion – Breach 4.5; No breach 2.2; No breach 7.6

12. The program falsely claimed that the National Heart Foundation had 'signed off' on *Catalyst's* evidence (*PM* 31/10/13) – Code of Practice sections 2.2 & 4.4

Complaint

Both the President and the CEO of the National Heart Foundation have complained that *'we are disappointed by Dr Demasi's subsequent accusations that the Heart Foundation in some way signed off on her 'evidence'. This is untrue and deeply offensive'*. We understand this complaint to refer to Dr Demasi's comments on *PM* on 31 October:

Transcript

> ***PETER LLOYD**: You also spoke in the program, both last week and this week, to the National Heart Foundation. Do you have their support?*
>
> ***MARYANNE DEMASI**: Can you be more specific?*
>
> ***PETER LLOYD**: Well, do they agree with the conclusions of the experts that you present in this program?*
>
> ***MARYANNE DEMASI**: The National Heart Foundation agreed that there would be people that are not at high risk of heart disease being medicated for these drugs and they would question whether or not these patients should be on those drugs.*
>
> ***PETER LLOYD**: Would it surprise you to learn that the National Heart Foundation's put a press release out today, saying that they are concerned with the program? How do you still say that they support these ideas if they're negating the program in press releases today?*
>
> ***MARYANNE DEMASI**: I think they're concerned the same as Emily Banks is concerned: that people will stop taking their medication unnecessarily. But when we actually presented the scientific literature to them then, they were certainly supportive of it.*

Assessment

Catalyst has advised that Dr Demasi had multiple discussions with Dr Grenfell on the phone before and after the film interview and on camera about the evidence that was going to be presented in the program.

The program states:

> *'When Maryanne refers to the evidence she shared with the Heart Foundation and they were supportive of it, specifically:*
>
> - *During the interview Maryanne quoted many studies that failed to demonstrate a link between saturated fat and heart disease. The National Heart Foundation agreed that the evidence is poor because the studies are difficult and complex to carry out.*
> - *The Heart Foundation agreed that substituting saturated fat for carbohydrates (as a result of the low fat revolution of the 70's and 80's) was detrimental.*

- *The Heart Foundation confirmed with Catalyst that statins are overprescribed*
- *Dr Grenfell agreed that people at low risk are being prescribed statins unnecessarily.*
- *The Heart Foundation agreed that the side effects of statins are underestimated because of the way the trials are designed.*
- *They agreed that the side effects of statins are underreported.*
- *They agreed that many doctors dismiss the side effects of statins when patients complain.*
- *Dr Grenfell agreed that cholesterol screening in children could lead to potential harms.*
- *Dr Grenfell agreed that the alternative theories of heart disease, i.e. inflammation, lamina flow causing atherosclerosis and bacterial infection were plausible but unproven explanations.*

This information is largely reflected in the extended interview on the Catalyst website and in the on air program.'

It is true that Dr Grenfell agreed with many of the propositions put to him by Dr Demasi and did not dispute many of her interpretations of the literature. However, to say that '*when we actually presented the scientific literature to them then, they were certainly supportive of it*' is a misleading oversimplification.

There were clear and important areas of disagreement between the National Heart Foundation and Dr Demasi and the overall proposition being presented in the programs.

For example, it is clear that one key area of disagreement related to dietary saturated fat. Dr Grenfell and the National Heart Foundation clearly stated their support for the hypothesis that dietary saturated fats raise blood cholesterol and that can cause heart disease:

> *One thing that has been proved conclusively is that a high intake of saturated fats leads to an increase in your blood cholesterol level. So that's proven to a convincing level. Then we take other studies on the other side of that and we look at what does an increased blood cholesterol mean and that gets complex because there's all the sub components. Which ones? Well the LDL ... are basically large globs of fat going around in your blood stream. If you have more of those, that is a higher level of those, you have a greater risk of having heart disease.*

This is in contrast to Dr Demasi's statement in the same *PM* interview that:

> *There's plenty of evidence in the literature to suggest that cholesterol is not the driving factor in heart disease. I felt it was important to highlight a lot of the literature that contradicts this hypothesis. http://www.abc.net.au/pm/content/2013/s3881383.htm*

Another key area of disagreement was the role of statins in primary prevention. In their email to Dr Demasi of 23 August the National Heart Foundation wrote:

The mass of evidence suggests that, compared with placebo, statins reduce the risk of death or cardiovascular events in populations without a history of CVD, irrespective of age and gender and across a wide range of cholesterol levels.

This is in contrast to the program which said:

Unless you've already been diagnosed with heart disease, then taking a statin won't help you live longer. It may reduce your risk of a cardiovascular event, but it may also increase your risk of developing something else, like diabetes. Either way, taking a statin won't extend your life span.

We note *Catalyst's* statement that Dr Demasi's remarks were made in a live radio interview which understandably required a simplification of the extensive correspondence between the program and the National Heart Foundation. *Catalyst* has explained that various statements from the National Heart Foundation were not used in the program for accuracy reasons. This is a separate matter to whether the National Heart Foundation supported the conclusions of the program and in fact points to a significant difference of view.

In our view, Dr Demasi's statement that the National Heart Foundation supported the evidence that the *Catalyst* program had presented to it was a material fact for the purpose of this program. That fact was not accurate. We are satisfied that News made reasonable efforts to ensure accuracy – for example, by querying the interviewee and presenting other perspectives – but we are nonetheless of the view that corrective action is required.

This inaccuracy did not, however, breach impartiality requirements regarding representation of perspectives. This is because the *PM* segment, considered in its entirety, clearly and correctly represented the National Heart Foundation's perspective. For example, the program included the following:

***PETER LLOYD**: The National Heart Foundation says it has serious concerns about the conclusions in Catalyst. In a statement, the charity is urging people not to change their diet or their medication until they speak to their GP.*

***PETER LLOYD**: Would it surprise you to learn that the National Heart Foundation's put a press release out today, saying that they are concerned with the program? How do you still say that they support these ideas if they're negating the program in press releases today?*

The editorial problem arose with Dr Demasi's inaccurate statement, not due to a partial misrepresentation of the National Heart Foundation's perspective by the *PM* program.

Conclusion – corrective action required, no breach 4.4