The Columbia lecture was originally scheduled as a debate between DH and Dr J Coyne. Dr Coyne subsequently lectured in Rutgers the following week and the email appears to cover the main points he made in that lecture.

Date: Tue, 15 Nov 2005 05:28:43 -0500
To: "Society for a Scientific Clinical Psychology"
From: James C Coyne jcoyne@mail.med.upenn.edu
Subject: Re: SSCPNET digest 3011

1. Before Healy began his career testifying in legal actions in which SSRIs are claimed to be the cause of suicide and homicide, he was richly rewarded by Pharmacia, a company attempting to capture a share of the SSRI market for their nonSSRI, reboxetine. His ability to bring large amounts of money to the University of Toronto was a factor in his being hired for a position there running a mood disorders clinic. When the US FDA withdrew approval for reboxetine and Canada was expected to do the same, Healy could not deliver the expected financial rewards to UT. He then gave a lecture that would convince many clinicians that they would not want to work in a clinic administered by him. Incidentally, in Wales, Healy administers an Electroconvulsive Therapy (or "shock" as some of his supporters would call it if they knew what he did) Unit.

Healy did not provide conflict of interest statements for the papers in which he made dubious claims for the superiority or reboxetine and he gave a very different account (as did his supporters Antonuccio and Carl Elliott) of what happened at UToronto, which was a basically a drug company deal gone bad. However, after my repeated public criticisms of him, Healy finally conceded in 2003:

"For the record, I am not aware of ever concealing my links to Pharmacia or any other pharmaceutical company. The initial overtures to me regarding a post in Toronto came at a meeting sponsored by Pharmacia, set up by individuals within the University of Toronto. Such links may well have looked attractive to the University of Toronto. (Healy 2003)"

But the evaded point is that Healy had not been disclosing these links either.

2. It is not true that Healy conducted his so called normal volunteer experiment before being involved in testimony concerning the alleged dangers of SSRIs. In testimony under oath (Miller v Pfizer) he concedes that he personally recruited subjects for that study; they were in a position to know his financial stakes in the matter; that these subjects were briefed ahead of time concerning how to tell the difference in the side effect profiles of reboxetine v SSRIs, effectively unblinding the study; one of the subjects who alleged behaved so strangely on SSRIs had showed symptoms first while on reboxetine and had just suffered the death of her grandmother; one subject for whom suicidality was claimed makes no mention of it in her study diary, but revealed it after extensive interaction with hospital staff working for Healy. Another published report on quality of life measures in this study makes no

mention of a claim of suicidality. I could go on and on about the defects of this "study", but it was cooked up when Healy needed it for his expert testimony.

3. Courts often adopt the rule that there needs to be a 2 fold increase in risk to establish general causality needed for product liability. Healy was dismissed as an expert witness in Miller v Pfizer because his results obtained from altering FDA data could not be replicated and had not been peer reviewed. Healy found a creative solution. He presented the doctored data in American Journal of Bioethics in a way that did not allow inspection of how he got his results. In responses to comments that his data differed from Khan's publishing of the same data, he conceded that he had doctored the data based on inside information. Technically, Healy was now "peer reviewed" in his claims, but not by anyone who could evaluate them. An editorial in AJOB subsequently denounced his misuse of the journal. Undaunted, Healy recently claimed in BMJ more than a 2 fold increase in risk associated with SSRIs. However, the journal later published a correction on his tables and these left the risk for SSRIs and TCAs as being similar.

4. Healy has been involved in a clash of financial interests, his and the lawyers and formerly Pharmacia on the one hand, other drug companies on the other. Yet, this struggle has been consistently misrepresented by him and his supporters as having COI located only on the other side. Healy's statement about his work as an expert witness in the NY Times article is misleading: legal work in the distant past does not explain or predict current behavior, nor does his past consulting relationships with Lilly or Pfizer. The misleading nature of Healy's current ahistorical coredump approach to disclosures highlights the limits of simply listing past involvements as a way of understanding current behavior. And if David Antonuccio wants to play mule and import Healy's claims to SSCPnet and elsewhere, these claims are nonetheless still tainted by Healy's direct financial incentives for making them.

5. Healy lies about his critics, including his allegations about my ties to industry. It may be true that the lies started with Antonuccio, but Healy persisted after I tried to correct him, and only shifted back to innuendo when continuing the lies threatened his credibility.

A number of questions arise in response to the above accusations from Dr Coyne:

JC: Before Healy began his career testifying in legal actions in which SSRIs are claimed to be the cause of suicide and homicide, he was richly rewarded by Pharmacia, a company attempting to capture a share of the SSRI market for their nonSSRI, reboxetine.

Where is the evidence for this statement?

Before Pharmacia was even formed I had given views in SSRI cases that these drugs had caused injuries. After giving views that Prozac had led to the outcome of suicide and homicide, I was a speaker on platforms for all of the major SSRI companies except Lilly, in addition to being a speaker for Pharmacia.

My original article on the issue of SSRIs and suicide was written in 1990 and the arguments that depression was being sold as a means to sell SSRIs is from an article written in 1990 and The Antidepressant Era which covers both these issues was written in 1995. Reboxetine, Pharmacia's drug was launched in Britain in 1997. My links to Pharmacia followed that.

JC: His ability to bring large amounts of money to the University of Toronto was a factor in his being hired for a position there running a mood disorders clinic.

Who in the University of Toronto has given Dr Coyne this information?

At no point in any discussions I had with the University of Toronto was there any discussion about bringing in money from pharmaceutical companies, so I am clearly interested in any information Dr Coyne can provide about what may have been going on that I was unaware of..

JC: When the US FDA withdrew approval for reboxetine and Canada was expected to do the same, Healy could not deliver the expected financial rewards to UT.

Who expected Healy to deliver financial rewards to University of Toronto? Unless Dr Coyne has informants inside the University of Toronto this is pure speculation – and speculation that doesn't fit well with the next point Dr Coyne makes.

JC: He then gave a lecture that would convince many clinicians that they would not want to work in a clinic administered by him.

Is this the lecture that was rated highest for content by the audience who heard it of all lectures delivered that day? Is it not the case that the person who most vocally criticised the lecture was someone who had nothing to do with University of Toronto?

JC: Healy did not provide conflict of interest statements for the papers in which he made dubious claims for the superiority or reboxetine

I did provide conflict of interest statements for articles on reboxetine in Primary Care Psychiatry but the journal chose not to publish them, and I have otherwise conformed to conflict of interest policies for any journals in which reboxetine related material was published..

JC: He gave a very different account (as did his supporters Antonuccio and Carl Elliott) of what happened at U Toronto, which was a basically a drug company deal gone bad.

The University of Toronto episode appears to map closely onto the Hastings Center Reports episode where Lilly withdrew funding from Hastings on the basis of an article written by me. Against this background is it surprising that Carl Elliott and others drew the conclusions they have drawn, which in the case of the Hastings Center incident appear fully warranted..

The only accounts that I have given of the events are in Perspectives in Biology and Medicine and Let Them Eat Prozac and these are agnostic as to the motives behind what happened.

JC: However, after my repeated public criticisms of him, Healy finally conceded in 2003:

Long before I ever heard of Dr Coyne I had acknowledged my links to Pharmacia and indicated that these may well have biased me, just as I think my links to SSRI and other companies have biased me. I have never claimed immunity from bias – indeed quite the contrary.

The following testimony under oath in Cassidy v Eli Lilly, taken in Chicago, on November 21, 2001, under questioning from A See, attorney for Lilly, posted on the AHRP website, in response to similar points made by a colleague of Dr Coyne from U Penn, speaks to this issue:

See: You have served as a consultant to Pharmacia and Upjohn regarding their antidepressant reboxetine?
H: Yes, I have.
See: You have done clinical work for them?
H: No, I have done no clinical trials. I have served as a consultant for them. I have been a speaker for them, but done no clinical work.
See: You have gone to speak in front of peer groups?
H: Yes.
See: About Reboxetine?
H: I primarily talked about the role of the drug acting on the [norepinephrine] system in the case of people who were depressed.
See: And it happens that that's the way reboxetine works?
H: Absolutely, yes.
See: And you have been compensated for that?
H: I have indeed.
See: Did you perform that work at the request of Pharmacia and Upjohn and your receipt of compensation from them for performing education functions and so on, did that make you a biased person?
H: I'm sure that the receipt of funds from Pharmacia and Upjohn as well as the receipt of funds from Lilly and SmithKline and others has biased me, yes. I think some sort of bias is inevitable. It is an issue of trying to manage that bias.

I have conflict of interest statements on SSRI and suicide articles dating back to 1994, long before it had become the norm to provide such statements.

JC: These subjects were briefed ahead of time concerning how to tell the difference in the side effect profiles of reboxetine v SSRIs, effectively unblinding the study

If subjects were not told of possible side effects would this not have breached informed consent norms?

Is there any evidence that this study was unblinded?

For the record the side effects that retrospectively distinguished between reboxetine and sertraline were not ones that subjects were informed of. They were informed of standard side effects such as nausea and sexual dysfunction, but these happened on both drugs. They were not informed of chilblains and cold sweats in the case of reboxetine and jaw dyskinesias in the case of sertraline, which occurred differentially between the drugs.

JC: One of the subjects who alleged behaved so strangely on SSRIs had showed symptoms first while on reboxetine and had just suffered the death of her grandmother.

Where does Dr Coyne get this from? It is not in any of the published accounts and as it stands is quite misleading. Of course all subjects who had previously taken reboxetine had had some side effects – such as nausea or dry mouth - but to insinuate as this statement does that this subject had been suicidal on reboxetine appears deliberately misleading.

JC: One subject for whom suicidality was claimed makes no mention of it in her study diary, but revealed it after extensive interaction with hospital staff working for Healy

Let Them Eat Prozac makes it clear that this subject was concerned that committing her thoughts on this to paper might lead to her hospitalisation. Is there a good reason to doubt this account?

Pfizer have been offered the opportunity to depose both subjects who became suicidal to explore the points made by Dr Coyne here. They have not chosen to do so.

JC: Another published report on quality of life measures in this study makes no mention of a claim of suicidality.

There was no reason why the second paper from this study needed to cover an issue covered comprehensively in an earlier paper and in a book then in press.

JC: I could go on and on about the defects of this "study", but it was cooked up when Healy needed it for his expert testimony.

Why would I need to cook this study up, when Pfizer have the Hindmarch healthy volunteer study, the details of which they refuse to publish to this day? This study remains unpublished but documents on public record now make clear that company officials reviewing this study linked treatment induced agitation to serotonin reuptake as far back as 1983.

JC: Courts often adopt the rule that there needs to be a 2 fold increase in risk to establish general causality needed for product liability. Healy was dismissed as an expert witness in Miller v Pfizer because his results obtained from altering FDA data could not be replicated and had not been peer reviewed.

There was so much confusion in the Miller case that it is difficult to know if Dr Coyne is adding to the confusion or not. One of the interesting features of the case was that Dr Concato, one of the independent experts, conceded that the notion of a 2.0 threshold for relative risk was meaningless in the context of an agent that might both reduce risk in some and increase it in others,

For the record, my original report contained no figure either greater or less than 2.0 for the risk from Zoloft.

I offered a figure of 2.19 in response to arguments made by Pfizer of the sort outlined by Dr Coyne here. Dr Coyne may want to work out a relative risk of suicide/suicidal acts from the data posted by the British Regulator on their website in December 2004 – or ask Drs Davis or Concato the other experts in Miller. The figure I get is 2.14 (95% Confidence Interval 0.96, 4.75).

Where is the evidence that Healy altered any FDA data in Miller other than in ways that Pfizer, Glaxo SmithKline and both FDA and MHRA have since subsequently accepted?

Thus this statement as it stands is wrong and again appears deliberately misleading..

JC: Healy found a creative solution. He presented the doctored data in American Journal of Bioethics in a way that did not allow inspection of how he got his results. In responses to comments that his data differed from Khan's publishing of the same data, he conceded that he had doctored the data based on inside information. Technically, Healy was now "peer reviewed" in his claims, but not by anyone who could evaluate them.

The AJOB letter is not included in the peer reviewed section of my CV. It is listed as a letter. The letter in AJOB included data that could be evaluated by anyone – and if my claims about this data were wrong I would have been subject to a legal suit from those whose practices were implicitly impugned and were in a privileged position to evaluate the data and the claims..

The letter in AJOB spoke directly to the ethics of placebo controlled trials making a point not at that point ever made in this debate. This was the sole motive behind that contribution.

Why would I need to depend on something like a letter in AJOB when I had a far more complete paper in press in Psychotherapy and Psychosomatics at the time?

JC: Healy lies about his critics, including his allegations about my ties to industry.

Exactly what lie have I told about Dr Coyne's ties to industry? And is it not the case that the issue of ties to industry or anyone else was in this case first raised by Dr Coyne? Can Dr Coyne be surprised if those he accuses of being biased, check and see whether he, Dr Coyne, is as pure and disinterested as his aspersions regarding others might suggest?