

# THE 7.30 REPORT

## Pan settlement opens door for huge class action

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Reporter: Thea Dikeos

**The \$55 million settlement between the Commonwealth and Pan Pharmaceutical founder Jim Selim has opened the door to a huge class action, that could cost more than \$100 million. Major losses were incurred by shareholders and businesses when Pan collapsed after the therapeutic goods administration suspended its licence and recalled its products in 2003. The legal battle has exposed some of the secretive machinations involved in the biggest drug recall in Australian history.**

### Transcript

KERRY O'BRIEN, PRESENTER: The biggest drug recall in the nation's history generated more headlines just a few weeks ago when it cost the Commonwealth \$55 million to settle a damages claim from Pan Pharmaceutical founder Jim Selim.

But the matter is far from over. Shareholders and other businesses incurred major losses when the Therapeutic Goods Administration suspended Pan's licence and recalled all its products in April 2003.

They are expected tomorrow to announce a class action against the Commonwealth which could run into an even bigger damages bill.

In settling the Selim case, the Commonwealth maintained it did not concede the specific claims that it had abused its power or acted negligently.

But the month-long court hearing raised what one former TGA insider describes as serious questions about the regulator's handling of the whole affair.

Thea Dikeos reports.

JIM SELIM: The public has to look why these people did this. \$1 billion was taken out of the Australian economy at that time.

THEA DIKEOS, REPORTER: When Australia's biggest complementary medicines manufacturer Pan Pharmaceuticals had its products recalled and licence suspended in April 2003 the collateral damage was significant.

MICHAEL SCHMIDT: There are people in this industry that were affected by Pan that are a shadow of the people they were, and I'm in that boat.

VAL JOHANSON, CONSULTANT: Many of the companies have still not recovered, some went out of business, many lost their homes, their families, their marriages and they're still coming to terms with it today.

THEA DIKEOS: Pan founder Jim Selim sued the Commonwealth, claiming the Therapeutic Goods Administration was negligent and had abused its powers.

After a month of hearings in the Federal Court, the Government settled the case with a \$50 million dollar payout.

ANDREW THORPE, LAWYER: How can a group of public servants, unchecked, bring down a public listed company in such a way? In our society it indicates a complete failure of whatever checks and balances there should have been to allow that to happen.

THEA DIKEOS: The TGA has declined 7.30 Report requests for an interview but at the time the Department of Health issued a statement saying "It did not concede to any of the specific allegations made in the civil claim."

While the Government has ruled out any inquiry into the actions of the TGA, at least one former insider argues the matter is far from over.

VAL JOHANSON: I don't think it's acceptable that they just say 'We're not going to have a review.' I think they need a proper, full inquiry into the TGA to see why it happened, how it happened and to make sure it doesn't happen again.

THEA DIKEOS: These days Val Johanson breeds prize winning alpacas.

Between 1991 and 1995 she was head of surveillance at the TGA. During the recall she was the Executive Director of the Complementary Health Care Council.

Now she's a consultant to businesses that were affected by Pans shutdown, in what's expected to be massive class action against the Commonwealth.

VAL JOHANSON: There is a real culture of fear between the industry and the regulator, so that I've actually had two companies, they are just too fearful to put their hand up for some dollars in case the TGA targets them.

MICHAEL SCHMIDT: They are completely unanswerable to anybody and there is this culture inside the TGA of repression.

THEA DIKEOS: Michael Schmidt calculates the closure of Pan cost his emu oil business almost \$300,000.

He will be one of hundreds of participants in the looming class action

MICHAEL SCHMIDT: I want to have an opportunity, whether it be in court, whether it be in an open forum somewhere, to have those people look me in the face and apologise to me for what they did.

THEA DIKEOS: The TGA and Pan had previously locked horns in the early 1990s, when then regulator prosecuted the manufacturer for failing to advise it of changes to its evening primrose capsules.

After Pan won on appeal, the TGA took the company to the High Court and lost.

ANDREW THORPE: There was a stream of thinking in the TGA that Pan escaped on a technicality, that it really should have been convicted and that it was just a question of time before they would be able to make good that technicality of 90s, and I think that's what happened.

THEA DIKEOS: In January 2003, Pan was back on the TGA's radar after its travel sickness tablet put 19 people in hospital.

Travacalm was recalled and tested by the TGA and found to have excessive amounts of some ingredients. But apart from that there had been no complaint against any other Pan product.

VAL JOHANSON: I am aware that Pan introduced new operating procedures to make sure that something similar could not happen again.

THEA DIKEOS: The Regulator conducted two audits of the Pan factory, the second in February, 2003,

But the TGA withheld that audit from Jim Selim and Pan until the day the TGA suspended Pan's licence, triggering the collapse of his company.

JIM SELIM: There was a shock when they turned on the 28th of April and said, well, here is a notice for suspend your company licence and here is a notice to recall all your product on the market.

(Excerpt, ABC News)

NEWSREADER: Consumers are facing the biggest drug recall in Australian history.

(End, excerpt)

THEA DIKEOS: At the time government ministers and bureaucrats were fronting the media to explain the action.

(Excerpt, interview, 23 April, 2003)

JOHN HOWARD, PRIME MINISTER: The advice is to listen to what the experts say and the experts are the Therapeutic Goods Agency. People running that are experts, I'm not.

(End, excerpt)

(Excerpt, interview, 28 April, 2003)

TRISH WORTH, FMR PARLIAMENTARY SECRETARY FOR HEALTH: The audit has found that their practices were unfortunately endemic.

DR JOHN MCEWEN, PRINCIPAL MEDICAL ADVISOR, TGA: I think that until people have had a chance to check the newspaper advertisement both tomorrow and later advertisements which may be at the end of the week or early next week, they should avoid taking their complementary or vitamin products, unless there is some very special reason for them to take them.

(End, excerpt)

THEA DIKEOS: Soon after the 2003 recall, Val Johanson met with TGA officials who admitted they hadn't tested any of the 6,000 recalled products.

VAL JOHANSON: It seemed to me obvious that you'd do some testing of the products just to confirm how significant and serious the problem was, I was told that "No, no, we hadn't done any testing because we

wouldn't know what to test for," which I found that an extraordinary response.

THEA DIKEOS: To suspend Pan's licence without notice the TGA needed to find that there was an imminent risk of death or serious injury.

The TGA's General Manager told Senate Estimates it took this action after seeking advice from an expert advisory group it had convened.

(Excerpt, 3 June, 2003)

TERRY SLATER, GENERAL MANAGER, TGA: We had advice that there was in imminent risk of death, serious illness or serious injury, we had to move immediately.

(End, excerpt)

THEA DIKEOS: Rita MacLachlan was the bureaucrat who signed the licence suspension on behalf of the TGA.

Five years later, under cross examination in the Selim civil case, she revealed that the Expert Advisory Group charged with providing the advice didn't use the crucial words "imminent risk" in their final report.

(Court transcript, 25 July 2008)

JUSTIN GLEESON SC, BARRISTER FOR JIM SELIM: Right. You knew that the panel of six had not concluded that there was imminent risk, that being the term in the statute correct?

RITA MACLACHLAN, TGA: Yes.

(End, excerpt)

THEA DIKEOS: Rita MacLachlan maintained in court that the TGA's actions were motivated by a desire to protect the health and safety of Australian consumers.

But the TGA's conduct as a drug watch dog was called into question during the court proceedings.

The February audit that had been withheld from Pan identified five alleged critical deficiencies which could result in harmful products being distributed to the Australian community.

Pan was not given the opportunity to fix or challenge the alleged problems, and millions of tablets and capsules continued to circulate in the community.

(Court transcript, 24 July 2008)

JUSTIN GLEESON: So for a five week period between the 21st of March and 28th of April, the largest manufacturer of complementary medicines in Australia had withheld from it a belief by the TGA that there were in place five deficiencies which had produced, or were likely to produce, harmful products; correct?

RITA MACLACHLAN: Correct.

(End, excerpt)

VAL JOHANSON: It seems to me if the TGA had concern about safety problems with any products being supplied to the public and exported, that the first thing to do would have been to give the company an opportunity to fix any problems or alternatively, if the products had been tested and shown to be faulty, they should have been recalled straight away, not continued to be supplied for another five or six weeks.

THEA DIKEOS: Pan's lawyer Andrew Thorpe says the TGA then proceeded down another path.

ANDREW THORPE: It then obtained legal advice, then decided to implement a new strategy which involved going out to Pan, getting more evidence to allow it to shut down Pan without notice so that Pan couldn't remediate those problems, if there were any, and Pan couldn't go to the Federal Court or any other court to protect its position.

THEA DIKEOS: Two weeks into the case the presiding judge summed up the dilemma for the Commonwealth lawyers.

(Court transcript, 25 July 2008)

JUSTICE EMMETT, FEDERAL COURT: If Mr Selim succeeds, his damages are going to be huge, aren't they?

DAVID BROGAN, BARRISTER FOR THE COMMONWEALTH: Yes your honour.

JUSTICE EMMETT: And the reputations of several senior Commonwealth officers are going to be completely destroyed.

DAVID BROGAN: Yes.

THEA DIKEOS: The 7.30 Report requested interviews for this story from the Health Minister Nicola Roxon and her junior minister Jan McLucas. Both declined.

But Senator McLucas issued a statement saying "The TGA and the Department are closely examining what lessons might emerge from the Pan proceedings, and what changes (if any) might be appropriate in light of that.

THEA DIKEOS: When the Commonwealth agreed to settle the Selim civil case, other senior public servants had yet to testify.

But with the impending class action, they will be summoned to court to explain their actions.

MICHAEL SCHMIDT: This is Australia, this is the most democratic country on earth, and no Australian citizen should be treated the way that myself and other people have been treated by this body.

KERRY O'BRIEN: That report from Thea Dikeos.

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