

Dear MP Roxon, MP Butler and The TGA Project Officer,

Hippocrates said "let food be thy medicine". This did not mean that our food should be regulated as dangerous drugs that need to be treated as potentially life threatening!

Hundreds of years later the observation of Hippocrates still stands, yet the Australian Therapeutic Goods Administration (TGA) want to go one step further and class our food as a hazardous medicine similar to dangerous synthetic pharmaceutical drugs? The TGA wants to do this by changing legislation that makes our food in capsule or tablet form a drug!

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<http://www.tga.gov.au/docs/html/cmec/section7.htm>

<http://www.tga.gov.au/cm/consult/cons-s7declaration.pdf>

Does this mean that Kellogg's Special-K in a capsule could soon be a drug or shredded wheat cereals?

The TGA states:

"In Australia, it has long been recognised that there is a legislative 'interface', or overlap, between foods and medicines for human oral consumption. As the food and complementary medicine sectors have evolved over recent years, a 'grey area' has unintentionally developed at this food-medicine interface. The confusion is due to certain areas of food legislation and therapeutic goods legislation overlapping in such a way that makes it difficult to determine which legislation should be applied in many cases."

The real reason for this overlap is that the TGA regulates health supplements as medicines. Health supplements should be regulated in a third category of their own, just as they are now or soon to be in New Zealand. If this happened then foods would not be regulated as drugs or medicines. This is the fault of the TGA's regulation and not the fault of the health supplement industry!

We use natural health products as foods and not medicine. Yes good food keeps us healthy but it is not a drug! We do not find the existing laws misleading or confusing as the TGA has insisted .

In fact, changing the law as the TGA is suggesting makes the new laws even more confusing.

We as consumers understand the difference between foods and medicines and we do not need the TGA to define this for us. We are intelligent human beings, we read the labels, we educate ourselves. It may be confusing to the TGA but it is not confusing to the public!

This law benefits the bigger health companies of which are mostly owned or majority controlled by drug companies. This proposal by the TGA will raise the costs of entry point into the health food market for small business, leaving a monopoly for larger companies.

Turning such food products into medicines is misleading on the TGA's behalf and serves also the financial interests of the TGA, as it generates more income with regards to annual audits and listing on the TGA Therapeutic Register of a health product. These costs will then be passed on to consumers.

For example, such products as Chlorella, Wheat grass, Barley grass and Spirulina, under the TGA's proposed plans, will become a drug and a medicine. These products will then become more expensive to purchase. This is outrageous!

People prefer these foods in a capsule form during travel, or because the taste may not be desirable to the palate, or just simply as it is easier to monitor how much of the food they have ingested, this does not make them a therapeutic good (drug).

Does this mean that the TGA will also categorise products, available from food retail, such as sodium saccharin tablets as a drug? This is the same sodium saccharin which has been linked to cancer (but still available to the public). Or will the TGA make exemptions for dangerous products like sodium saccharin to be freely available as a food?

Over the years the TGA and its officers seem to have forgotten about their original charter, and now we are seeing what is commonly called "regulatory creep".

The whole primary raison d'être for the TGA is to keep us safe from dangerous drugs, which the TGA is not doing such a good job of. Remember Vioxx? The TGA did nothing! Merck Sharp & Dohme eventually pulled the Vioxx off the market voluntarily after it had already killed 50,000 people
(<http://www.theage.com.au/articles/2004/10/27/1098667790205.html>)

The TGA should keep its hands off our foods! Food is a food and drugs are potentially dangerous products produced by drug companies! There is a large difference and we do not find the definition confusing, nor should the TGA!

The amendments to Section 7 of the Therapeutics Goods Act should not be implemented in any form.

We call on the Federal Minister for Health and the TGA to withdraw this proposal.

Petition signatories

Mikki Taylor	Sue-Lyn Ryan	Cherie Miles
Mary Mcnamara	Angela Austin	Robert Flemnig
Susan Short	Mark Stevens	Allan Dimond
Shannon Fletcher	Kay Webster	Brian Stanton
Giovanni Doro	Nina Peheim	June Parsons
Nikolas Carfrae	Rosemary Coleman	A Nolan
Tania Kirby	Mary Ahern	Matthew Hutchinson
Allistair Chapman	Doreen Wheeler	Janine Turner
Rachelle Willis	Dorothy Schneid	Ben Vickery
Lawrence Sim	Ivor Rich	Ursula Curnow
Tracey Mackenzie	Robert Davies	Robyn Matthews
Scott Picken	Kenneth Scott	Tom Grimshaw
Chris Morgan	Narelle Milekic	Dianne Norris
Brent Rodgers	Giles Mamet	Teodora Nagy
Joy Hodson	Sarah Chamberlain	Colston Vowles
Jeremy Dive	Lan Tran	Chris Gregory
Stan Adamson	David Arnold	Diane Mills
Natarsha Tyson	Linda Vij	Daniel Lawson
Sam Prior	Duncan Mcdonald	Shelly Mcaulay
Sherlene Turner	Roy Gillrie	Tony Stanley
Kim Sheppard	Allan Dewar	Graeme Knight
Margaret Phillips	Val Wicks	John Mayger
Colin Bishop	Melinda Lewis	Kerry Healey
Geesje Dekker	Rebecca Crooks	Rachel Coupland-Evans
Melissa Murdoch	Laura Diaz-Icasuriaga	Anatelyah Harari
Amanda Lalor	Ian Bundy	Lorraine Collins
Marge Kelly	Ross Phillips	Liz Spittall
Beverley Mcgeachy	Catherine Fleay	Juliette Williams
John Samphier	Coralie Ryan	Jarrold Breckenridge
Tania Diedericks	Verna French	Kalista Carfrae
Michele Cartwright	Pierre Petoud	Julie Woodman
Dawn Tinsley	Marj Drury	Camilla Nova
Robert Callaghan	Lynette Kinnear	Jeanette Wilson
Matt Saunders	Sandra Coffey	Anne Van Strijp
Michael Klein Ewin	Helen Brennan	Jane Lush
Arthur J. Mueller	Marilyn Andrew	Lynda Cord
John Wilson	Rosemary Vaher	Ken Uzzell
Elizabeth Foster	Sandy Jeudwine	Katherine Eagles
Rick Shortland	Maureen Smith-Tan	Ross Cowling
Dimitra Dokos-Schoell	Russell Lange	Nick Fehlberg
Justine Weatherill	Pamela Atkinson	Ian Modistach
Lorinda Panton	Pat Sternbeck	Larina Downey
Mary Cardy	Graham Duck	Ruth Sandri
Dolph Cooke	Michael Murray	Mark Simpson
Lynne Grimsey	Fred Walton	Penny Jacobsen
Wendy Stewart	Tania Craig	Vicki Lowing
Richard Kent	Courtland Oakes	Maree Nolan
John Marsden	Heidi Tribolet	Tamara Baeva
Jennifer Reuterink	Jerry Valenta	Bev Curtis-Flynn
Bert Gay	Susie Wyles	Michelle Ovens

Petition signatories

Antje Nebel	Julie Tyldesley	Eva Major
Zen Gumedé	Jack Westbury - Driscoll	Steven Bowins
Laurie Weller	Vanessa Da Silva	Sandra Camm
Debbie Faichney	Scott Barbour	Jack Verbeek
Sharon Stuart	Marilyn Williams	David Horwood
Jason Webber	Carole Booth	Andrew Blease
Marion Corby	Chris Bromley	Ian Jenkins
Caroline Taylor	Cari Ferris	Paul Homer
Cath Montague	Chris Power	Julie Head
Malcolm Pendergast	Beatrice Nabytowicz	Katherine Jones
Hiromi Maskell	Ramiah Selwood	Eric Rodda
Jane Ainsworth	Trevor Savage	Ivy Toh
John McNair	Annmaree Miller	Scott Divine
Jennifer McBryde	Michael Hutchinson	Julianne D'Auvergne
Emma Wright	Peter Sen	Samantha Hayward
Stafford Lowe	Vanita Hayzelle	Mario Serra
Namik Omerspahic	Catherine Spanner	Laurel Vale
Mark Spedding	Linh Tang	Bruce Fryer
Caolyn O'Brien	Frederick Large	Donatella Mecham
Michael Mazur	Iona Kentwell	Sarah White
Estelle Judah	Mario Psaila	Sonja Hardy
Frank Zamburro	Roy Fogarty	Rhonda Walsh
Chris Barnes	Noela Latter	Bert Swalue
Wendy Johnson	Douglas Harber	Judith Guzys-Mcauliffe
Allan Meers	Pat Weller	Wendy Bryan
Peter Robins	Lee Van Netten	Bruce Thorpe
June Tornabene	Anthony Johnson	Kevin Chinnock
Patricia Shears	Leonie McDonald	Bronwyn Kennedy
Gloria Hartman	Laura Collins	Christina McDonald
Gavin Webber	David Brown	Michael Smith
John Heasman	Neil Rosenberg	Helen Betts
Leisa Wheeler	Judith Chapman	Judith Prior
Stefan Talmatzky	Adrian Saul	Richard Dion Wilson
Meredith Swalue	Brigit Charles	Kristy Grogan
Simon Emmott	Angela Perin	Lee Chancellor
Nura Tashiro	Kim Britton	Andy White
Grant Gamble	Karen Douglas	Leonie Eulenstein
Janet Whineray	Marie Bellenger	Andrew Shore
Suzy Gneist	Wallina Sekula	Patricia Wheeldon
Jan Brenton	Patricia Zutt	Vesna Pinter
John Springett	Kerstin Haddad	Lesley Sullivan
Johanna Chadwick	Rebecca Thom	John Hanes
James Terry	Josie Schwerdtfeger	Michael Randall
Alison Eastland	Monique Gregory	Martin Roberts
Julie Sheehan	Caroline Goode	Deborah Howlett
Josephine Wright	John Ashby	Jenny Rice
Anthony Smith	Kathleen Mcerlain	Peter Stanford
Julie Fox	Peter De Ruyter	Melissa Trigar
Helen Lu	Terri Groth	Roslyn Gore
Raquel Andre	Rosemary Nolan	Cathy Dickson

Petition signatories

Heather Mckenzie	Joan Strahan	Julie Bullard
James Brown	Matthew Davidson	Ann Weller
Renate Delaforce	Kris Barrett	Caroline Andrew
Tatiana Schild	Peter Thiele	Benjamin O'Brien
Jacquie Schell	Delena Gaffney	Barbara Middleton
Jernin Yates-Round	Doug Lindsay	David Bryden
Lionel Ortell	Rachael Otto	Gillian Robinson
Shaun Driscoll	William Hendy	Colin Kelsall
Sandra Downs	David Bridgman	David Jennings
Phillip Atkinson	Brendan Murdoch	Anjel Obryant
Frank Saez	Sarah Rea	Rose Morris
Neesa Dann	Glenn Wright	Colleen Clark
Sabine Jansch	Sandra Barnsley	Gwen Daffy
Will Lardner	Luke McMahon	Beata Witkowski
Kamala Devii	Rosalie Walker	Maggie Wilson
Rebel Lorenz	Diddy Schaap	Drew Fisher
Susan Woledge	Lesley Lee	Glenn Roberts
Cheryl King	Darilyn Love	Victoria Rose
Gregory Ockenden	Carol Ryan	Kerrie Poncet
Jeanette Wagner	Robert Barrowcliff	Christine Phethean
Caleb Rudd	Brett Durston	Elizabeth Mulquiney
Ingrid Rodden	Elina Burchey	Jane Anderson
Sue Muspratt	Kim Cooper	Kathleen Muller
Helen Belcher	Judy Nicol	Josephine Beams
Devon Harris	J Renauer	Johannes Grobler
Naomi Seiler	Olga Beliak	Cheryl Morden
Hugh Wallace	Kaz Genders	Abby Eagle
Ross Stacey	Diane Mccann	Michael Threlkeld
Patricia Cheetham	Charles Drace	Denise Riseley
Judith Williams	Pauline Santillo	Beryl Warne
Kay Mckenzie	Jeanette Baughurst	Christine White
David Brace	Kris Wright	Patricia Barron
Roxanne Iwinski	Peter Kelly	Jen Beutel
Sarah Mcdonald	Wayne Martin	Raz Solo
Christine Edwards	Frank Demaria	Pauline Rose
Dean Jefferys	Grant Robb	John Doecke
Julie Damant	Margaret Field	Andrea Borbas
Jerry Kobylski	Patty Stuart-Macadam	Norman Hando
Anna Morten	Jodie Davies	Rosemary Smith
Ed Love	Jason Carmichael	Celeste Hinton
Andrew Verity	Priscilla Saxon	Brian Hay
Mike Bonaccorso	Rod Pallot	Uli Kruger
Joanne Herbert	Marti Fordyce	Keith Carstens
Pamela Grimes	Gregory Brown	Claire Sarandis
Trevor Hywood	Daniel Dappio	Ian Manson
Josie Vittiglio	John Rufus	John Nielsen
Sandra Kane	Carol-Anne Brand	Carol Skeggs
Garry Lawler	Kirsten Pearson	Jayden Melit
Sandhi S	Madelaine Bishop	Brad Gilbert
Tony Milekic	Robyn Groves	Andrew Cox

Petition signatories

Dr Darag Rennie
 Terrie Beresford
 Robert James Simpson
 John Taylor
 Pete Malavisi
 Chloe Montague
 Stuart Atkinson
 Pauline Stringer
 Anne Hill
 Mike Haffenden
 David Holbrook
 Steven Brodie
 Jewelli Dollman
 Jack Coffey
 Dirk Roelofs
 Ingrid Moyle
 Kaye Barr
 Angie Godwin
 Anne Macindoe
 Jill Peart
 Tina Jasheya
 John Vladich
 Dianna Hetherington
 Reginald O'Loughlan
 Ron Cummings
 James E. Bryan
 Mary Anderson
 Bruce Kinnersley
 Susan Klohk
 Stuart Gibson
 Robert Henderson
 David Laws
 Peta Richards
 George Steele
 Tara Shaw
 Kuatarina Mount
 Cameron Burnell
 L. Ray
 Zoe Lockley
 Sheila Hurst
 Linda Holt
 Jolanda Koedood
 Lynn Preece
 Scott Concannon
 Joshua Geyl
 Liz Pennbowen
 Julie Willoughby-Smith
 Simon Dannapfel
 Arnold Ward
 Sandra Bettison

Anne Gibson
 June Robertson
 Nell Thayne
 Jeffrey Rose
 Frank Harrison
 Janet Redbond
 Gail O'Loughlan
 Nathan Davis
 Barry Waddell
 Pauline Rea
 Jon Yeo
 Elizabeth Ferris
 Merula Dowding
 Becky Head
 Leonard Fernando
 Liita Kalimeris
 Liz Butler
 Christine Olsen
 Jan Dawe
 Janette Roberts
 Valerie Bond
 Leonard Clampett
 Kenneth Sinclair
 Ray Hammat
 Kalinka Booth
 Chris Evans
 Sally Roth
 Neil Ashton
 Alan Cook
 Sue Webb
 Juliette Mcconachy
 Zvonko Kostov
 Joyce Rawson
 Lisa Mears
 Rose Giudici
 Zoe Dodds
 Libby Ivens
 Kristine Lye
 Mark Thornquest
 Marcia Pitman
 Carol Williamson
 Jarmila Slovak
 Denise Taylor
 Jennifer Braun
 Huirangi Lazanis
 Linley Anderson
 John Colwell
 Peter John Charlick
 Pip Rose
 Helene Evans

Derek Hooper
 Anastasia Salih
 Bronwyn Lockhart
 Richard Wynne
 Karen Shea
 Eric Livingston
 Les Harris
 Jane Toxward
 Tara-Jade Brown
 Raelene Jury
 Van Nguyen
 Rachel Block
 Athina Geordin
 Joshua Kim
 Charles Underwood
 Ngoc Dung Tieu
 Freedom Garvey-Warr
 Tim Heckler
 Danielle Angel
 Werner Schmidlin
 Margaret Smyrnis
 Kathryn Rae Mccloghry
 Kaz Smith
 Sue Gunn
 Ric Halstead
 Garth Fortune
 Jeni Saunders
 Kelly Mcmeeken
 Roanna Pepper
 Trevor Thomson
 Emily Porter
 Joy Shepperd
 Niikee Schoenodrfer
 Daniel Paitson
 Michael Mclennan
 Linda Ault
 Paul Turner
 Marja Boyce
 Mark Purcell
 Kate Golle
 Catherine Westbury
 Yvonne Pearce
 Ian Hobbs
 Leonard Fernando
 Bruce Gunn
 Nigel Greenhalgh
 Dr Allan Lambert
 Jill Bramhil
 Dwayne Hickman
 Carolyn Karski

Petition signatories

Richenda Bridge	Peter Ezzy	Gordon Baulch
Len Riseley	Romilly Brickell	Nicole Setton
Jacinta Binns	Donna Russo	Barbara Manassero
Christopher Down	Jonathan Carmichael	Brian Elmer
Maria Korps	Jeffrey Chiang	Lars Andersson
Carol Champion	Jason Simpson	Heather Tapodi
Bill Lee-Emery	Cheryl Yamazaki	Anton Klemens
Jan Sooby	Michael Servais	Mark Barone
Karen Christie	Anna Pemberton	Renee Middleton
Robert Moore	Josephine Reid	Randal Love
Beth Nicol	Fiona Arnott	Ceila Lariba
Ruth Rendely	Kathy Christodoulous	Peter Kroll
Patricia Gledstone	Rosemary Keating	Raquel Smith
Nerine Taylor	Jane Leonforte	Tamsyn Holdaway
Karmen Novak	Louis Gebhardt	James Hazell
Keir Sooby	David Mills	Tracy Leech
Ifeanna Tooth	Darlynn Gillrie	Ray Burrows
Vincent Collova	Kirsten Mort	Elizabeth Dick
Daphne Maurer	Alex Powell	Charlotte Le-Cocq
David Still	Zvone Vodnik	Blair Andrew
Ellen Dunlop	Yves Lehmann	Jeanette Beauchamp
Patrick Mccarthy	Tony Lambert	Leo Lenders
Jenna Bosley	Carolyn Smith	G. Matthew Norman
Heather Steele	Sally Wearne	Ross Perry
Steve Lockie	Linda Seang	Melvyn Mills
Lenore Cannon	Nicole Hannan	Lel Doon
Nicolette Bryan	Maree Darby	Elizabeth French
Keyan Sarlak	Tanya Gates	Judi Defina
Trevor Maskell	Felicia Sandover	Linda Webber
Anne Llewellyn	Rhys Drummond	Mark Gregory
Marcia Millard	Allison Waldock	Paul Fleay
Tammy Sooveere	Olivia Edwards	Sasa David
Alison Eastment	Caroline Whittle-Herbert	Karl Ahrenfeld
Gordon Carruthers	Belinda Hude	Dawn Powell
Peter Zyczynski	Phillip Moon	Judith Dickens
Natalie Reynolds	Anita Jorge	Albert Hunter
Tessa Finney-Brown	Yuri Szilasi	Suzanne Mckinnon
Basil Lancaster	Mary White	Colin Soper
Marshall Mcadam	Susan Rennie	Linnie Lambrechtsen
Helena Drummond	Margaret Howe	Stanislava Klose
John Gillies	Kevin Whelan	Debra Forbes
George Blazek	Margaret Sullivan	Belinda Morris
Nick Dolley	Beverley Obermayer	Rod Delaforce
Grace Field	Michelle Brasell	Dwayne Page
David Zuric	Benjamin Mcavoy	Mia North
Michelle Bower	Graham Cook	Raymond Bate
Gaele Maat	Almeda Peer	Kevin Hodges
Mark Trinca	Sarah Coffey	Judith Hogg
Ruth Higginson	Sue Mylius	Rod Sylvia
Victor Besz	Janenne Kornfeld	Joe Sarlak

Petition signatories

Natalie Gronow	Judi Jaques	Joanne Douglas
Audrey O'Donohue	Donald Wilson	Glynnis Surtees
Charlie Allen	Barry Townsend	Beau Deeley
Joseph Breschi	Brian Schaefer	Charles Filet
Veronica Miles	Glen Ingram	Bryce Swadling
Chris Ardill-Guinness	Philip Middleton	Lynne Armstrong
Julia Page	Anthony Golle	Vanessa Bagley
Mark and Angela Hoggett	Elizabeth Dray	Ethne Gautier
Louisa Koche	Dianne Dewson	Vojta Brodecky
Jane Mccue	Eloise Anderson	Roseanne Morgan
Tammy Reid	Hamish Sutcliffe	Susan Hamilton
Joanne Dilly	Lorraine Parker	Noel Gomersall
Mike Hetherington	Ken Wilson	Viola Wellenreiter
Linda Shewan	Alison Flanagan	Jennifer Goh
Neil Mcgrath	Marcille Cameron	Julie Simpson
Grant Hughes	Kim Stewart	Robert Hoogenboom
David O'Dea	Faye Hall	Linda Stratford
Deveraux David	Barbara Morgan	Nerida Mills
Brett Archer	Phillip Strahan	Sophie Lloyd
Michele Stephens	Peter Caughey	Annaise Novak
Laurence Cox	Sandy Sanderson	Raphael Verkest
Carol West	Terrence Bishop	Dr. Michael E. Dipaul
Peter Young	Karin Ewence	Sally Gray
Dorothy Adair	Jennifer Nova	John Waters
Stephen Norris	Nadeya Maystrenko	May Boisen
Jacqui Hollitt	Richard Nilsson	Christine Bennett
Julie Harrison	Mary Wilson	Jan-Marie Brooke
Paul Mischefski	Tim Welch	Angela Copeland
Marguerite Porter	Doris Were	Diana Cummings
Kobi Hirsch	Steve Lumsdaine	Lance Sutcliffe
Christine Zsizsmann	Martine Negro	Judith Corner
Sharon Prior	Louise Stephen	Althea Bell
Diane Styles	Eve Hansen	Christopher Ind
John Graham	Alain Romary	Roslyn Benson
Iesha Delune	Doug Holmes	James Hopkins
Beau Lester	Kim Timmerman	Nik Filbry
Catherine Smith	Toni Smith	Chris Morgan
Pamela Thomson	Gail Kennedy	Theresa Babcock
Penelope Scull	Mario Beetz	Kim Boyd
Beverley Baker	Cheryl Gilbert	Deanne Gregg
Enrique Wuest	Robin Foley	Barbara Casbolt
Deb Brice	Anne Masi	Sheena Worrall
Kathy Devos	Candy Raymond	Katherine Maslen
Willow Francis	Fran John	Sue Collins
Megan Mckay	Bill Bowden	Kate Broomhall
Daniel James	Atmo Kusseler	Naomi Burton
Huy Tran	Sandra Sharp	Deanna Chambers
Eeva Sheedy	Teresa Allen	Catherine Narbett
Elizabeth Daunt	Beppie Van Maanenber	Harry Schuster
Carleen Sing	Cathryn Nitschke	Lynda Williams

Petition signatories

Lynette Estreich	Ashtweth Palise	Mary Barton
Glenn Batten	Penny Carrier	Elaine Hickman
Tahns Rangi	Tasha David	Paul Stuart
Frank Agius	Gregory Damato	Janet Taylor
Hayley Wallace	James Hutchinson	Carole Pendergast
Diane Akers	Angus Grogan	Dallas Broad
Tanya Erwin	Carole Hubbard	Berny Doherty
Merryl Cowie	Colette Sebat	Marlena Bloomfield
Cheryl Kemp	Leonie Milne	Isana Reid-Gray
Frank Legge	Lisa Clarke	Kay Paki
Audrey Harrington	Irma Roskam	Susan Living
Jana Kingston	John Trieu	Ursula Radford
Sam Zylberberg	Jennifer Cleary	Peter Barraket
Peter Thomas	Daniel Rogers	Jaap Roskam
Maria Frizziero	Meg Mills	Bruce Bramhill
Susie Pitt	Michel Kir	Barbara Lockwood
Jack Katz	Stafford Hall	Tessa Martin
Douglas Haack	Sian Henderson	Deborah Bezjak
Karen Fisher	Hilary Stevenson	Jay Tunnell
Annette Angell	Kim Watson	Gregory Bold
Adele Usci	Paul Wilson	Martin Sharp
Geoffrey Leigh	Mark Walton	Robert Draper
Alan Boyd	Stephen Kemp	Kerrill Chambers
Cyril Barlow	Henri Virtanen	Val Noble
Terence Carfrae	Alexander Kowal	Christine Hildebrand
Keith Langston	Vanessa Nixon	Hazell Carver
Ace Gregory	Isabell Shipard	Sandra Hanna
Jennifer Tao	Brett Laboo	Laurence Jones
Eve Adam	Neil Schell	Ross Gardiner
Linda Lyons	Brian Speight	Leo Wheeler
Stefan Smon	Margaret Matthews	Jenny Chou
Linese Norrish	Hans-Harry Behrends	Glenda Anderson
Hendrik Van Schie	Kath Terauds	Lynden Thomas
Philip Higson	Flora Trinca	Fran Schwarz
Lesley Johnson	Marilyn Vine	Bill Kilvert
Nick Poranek	George Liebmann	Rosalie Jager
Hugo Korps	Sandra Duncan	Tess Mitchell
Joanna Harrison	Julie Chadwick	Karen Coates
Donald Edmunds	Donald Watts	Shane Sauter
Jane Abberfield	Chris Martin	Regina Delay
Brett Hayes	Katrina Thorpe	Wendy Slee
Peter Bywater	Will Hof	Jim Tourtsakis
Lorraine Kay	Kathleen Buckley	Michael O'Donnell
Jennifer Cargill	Chrystal Di Camillo	Brenda Slavoff
Wendy Manier	Mashenka Barlag	George Webeck
Deb Dillon	Elaine Tscharke	Jenny Schuster
Margaret Althaus	Mardy Penrose	Christiaan Wililiam
Ron Otten	Soren Kierkegaard	Jane Beeby
Stuart Rowe	Sylvia Stipic	Geoff Baker
Lindy Davies	Monica Anderson	Julie Lehmann

Petition signatories

Lynn Stanfield
Jennifer Heywood
Nathan Watson
Tina Trivett
Deborah Palacios
ma

Dennis Stanbridge
Vincent Huang
Odin Mackay
Jane Minelli
Vida Barrett

Maria Kuchel
Aggie Michalska
Christine Pallot
John Wass
Nina Ara