Dear Senator Bernardi

Re; Senate Committee Inquiry on Men’s Health

It is with regret that the 60 page submission I was preparing for this inquiry was lost in the recent Kinglake Bushfire, along with all other property and possessions of mine, and I now submit an abbreviated submission. Under such personal adversity, I believe this submission falls within the Terms of Reference.

It is with pleasure that this submission be accepted in accordance with your Notice Of Motion (276) published in November 2008, some 5 months after a Private Member Motion was read in the House of Representatives.

The Member for McEwen (Ms Fran Bailey) read a very emotional speech in the House (Committee Room) on 16th June 2008, supported by the Member for Moore, (Dr Mal Washer) and further with bipartisan support by the Rudd Government - expressed by the Members of Page, (Ms Janelle Saffin) and Dobell, (Mr. Craig Thomson)

It is with my pleasure that I submit the following Submission on behalf of myself and all other (then) boys and men treated with Human Pituitary Hormones, unofficially, and not recorded, under the Australian Human Pituitary Hormone Program, and who have suffered, with both short term and long term side effects to the male endocrine system as a result of such Human Experimentation, and with such side effects that are irreversible.

Approved Recipients of Human Growth Hormone or Human Pituitary Gonadotrophin were subjected to a Senate Inquiry in 1993, known as “The Allars Inquiry”, however – unapproved and/or “Off Program” recipients who were not included in the Allars Inquiry, and whom were not disclosed to the Department of Health and Aging, who are at the same risk of CJD, and were never advised of their risk, particularly unrecorded recipients of hPG at Prince Henry’s Hospital in Melbourne – hundreds of males. The Senate now records (1998) the “Allars Inquiry” was misled.

It is these Males who were “overtreated” with Human Pituitary Gonadotrophin, who were “overstimulated” through invivo experimentation, with batches varying and causing dire consequences to physical, mental and reproductive health - those who were exposed to anabolic steroids (a carcinogenic) as a Growth Promotant with severe side effects. Particular Recommendations were presented and submitted to The Minister for Health by Professor Margaret Allars in 1994, and further explored by the Senate Affairs Reference Committee in 1998. Of these numerous recommendations, I draw particular reference to Recommendation 5 stating

That the settlement offer should not preclude a plaintiff making any future claim in relation to: (a) Other physical illnesses contracted by recipients which may be related to long term side effects of HPH treatment

This submission is dedicated to the Infant boys, Toddlers boys, Prepubescent boys, Teenage boys, Young, Middle Aged and Elderly Men aged 2 to 101 – who were treated under such experimental Programs, exposed to Endocrine Disruptors during the 1970’s, particularly those whom were castrated and sterilized by the Australian Government and/or representatives engaged under the Health Act 1958. Such Section with the Act has since been repealed so that the “experimental nature” of “The Program” cannot happen again - following the “Allars Inquiry”. This does not repeal or repair the ongoing side effects. In particular, I dedicate this submission to the memory of the child who lost his life under these experimental programs at Prince Henry’s Hospital during the 1970’s.

Please accept my gratitude with appreciation with your efforts in this forthcoming Inquiry.

Yours Faithfully

Michael O’Meara

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1 Reports, Dr N. Tonti-Fillipini (2008), Dr O’Collins (1979), Dr Burger (1972/3)
2 “As treatment doses and frequency were varied, he was effectively castrated, with his testes so damaged that puberty was then delayed to such an extent that he was treated with anabolic steroids to induce puberty”. House of Representatives Hansard 16th June 2008
4 The Testes – Clinical and Experimental Studies, 1983, Burger HG, de Kretser DM
Submission to

Senate Committee Inquiry on Men’s Health

January 2009

“Endocrine Disruption – Evidence Based Causation - Anxiety, Depression and Cancer/s”

Destroying Male Health

Author - Mr. Michael O’Meara
Dedicated to the Men and Boys treated with Endocrine Disruptors (Human Growth Hormone/hPG\textsuperscript{5} and Anabolic Steroids\textsuperscript{6},) as a “Growth Promotant” at Prince Henry’s Hospital\textsuperscript{7}, Melbourne and the Kingston Centre, Cheltenham during the 1970’s.

In Melbourne, from the early 1970’s, prepubertal and adolescent boys with a prediction of ‘short stature’ were treated with synthetic androgens (the anabolic steroid –oxandrolone, aka Anavar) to accelerate their growth.

The experiment/s failed, leaving boy/s with stunted growth, ectopic, atrophied and crushed testes, including endocrine disorders, gynecomastia, hypogonadism, sterilization, cancer and prostate disease as teenagers and into Adult life. Those who were castrated as children in the 1970’s under “The Australian Human Pituitary Hormone Program”, in unethical, unapproved, experimental programs, without disclosure or consent, which concludes in premature death.

Acknowledgement -“It is also important to acknowledge the participation of numerous patients in the studies described. Without their help, clinical research would not be possible and quite often their misfortune\textsuperscript{8} prompted a new study or helped to elucidate a novel concept”\textsuperscript{9}

\textsuperscript{5) Recipients of Non CSL Pituitary Hormones whom were of “short stature” who aren’t aware they are recipients of pituitary hormone imported into Prince Henry’s Hospital from Bethesda, Maryland U.S.A. and Cambridge. England. Non CSL HPG was manufactured at Prince Henry’s Hospital in Melbourne and never disclosed to the” Inquiry into the Use of Pituitary Hormones and Creutzfeld-Jacob Disease”. Prof. M. Allars 1994. HPAC Member/s manufacturing their own HPG as early as 1968 at Prince Henry’s Hospital in Melbourne, with such documents not tabled in the “Allars Inquiry”

\textsuperscript{6) Oxandrolone administered “was not to induce puberty, not to encourage growth” – Dr * *****, Endocrinologist.

\textsuperscript{7) 466 males were treated at PHH and weren’t disclosed to the Dept of Health and Aging when requested in 1993 during the “Inquiry into the Use of Pituitary Hormones and Creutzfeld-Jacob Disease”. M Allars 1994, as these were not manufactured by CSL. Correspondence from Dr Frank Peters (dec.) and Dr Wes Whitten (expert witnesses to “The Allars Inquiry”) to M. O’Meara

\textsuperscript{8) House of Representatives Hansard 16 June 2008.

\textsuperscript{9) The Pituitary and Testes – Clinical and Experimental Studies 1983. Burger HG. De Kretser DM
During the early to mid 1970’s, prepubertal, pubertal, adolescent and adult males were treated with “test batches” of Human Pituitary Gonadotrophin (HPG) and were “overtreated” inflicting castration upon the gonads. As a result the prepubertal boys were also treated with anabolic steroids and were inflicted with prostate disease as teenagers.

There has been no follow up to these males treated at Prince Henry’s Hospital who have incurred male endocrine disruption including cancers, clinical depression, testicular atrophy, cysts and hypogonadism.

I submit herewith a copy of the House of Representatives Hansard for further explanation.

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276—

1. That a select committee, to be known as the Select Committee on Men’s Health, be established to inquire into and report by 30 May 2009 on:

   General issues related to the availability and effectiveness of education, supports and services for men’s health, including but not limited to:

   i. level of Commonwealth, state and other funding addressing men’s health, particularly prostate cancer, testicular cancer, and depression,
   ii. adequacy of existing education and awareness campaigns regarding men’s health for both men and the wider community,
   iii. prevailing attitudes of men towards their own health and sense of wellbeing and how these are affecting men’s health in general, and
   iv. the extent, funding and adequacy for treatment services and general support programs for men’s health in metropolitan, rural, regional and remote areas.

I rise to speak to the motion listed in my name. On 1 November 1971, the Melbourne Herald ran a story that reported on scientific work being conducted at Prince Henry Hospital that was a breakthrough in the treatment of abnormal growth in children. A means of measuring children’s growth hormone produced in their pituitary glands enabled doctors to ascertain the height stature of children.

The treatment developed to correct predicted stature abnormalities was to administer a human growth hormone known as HGH that was extracted and collected from cadavers. This program was known as the Australian Human Pituitary Hormones Program, known as AHPHP.

The human growth hormone administered to these children was in fact the same hormone, human pituitary Gonadotrophin, known as hPG, which was administered to over 1,500 women and an estimated 60 men for infertility. Thanks to the member for Higgins, the tragic issue of the connection between hPG and the fatal disease of Creutzfeldt-Jakob disease has been recognized as a public health issue.
As well as being treated with hPG, unknown numbers of prepubertal and adolescent boys with a prediction of short stature were treated with synthetic androgens or steroids to accelerate their growth after being primed with hPG. This caused hypogonadism, including prostate disease, in unknown numbers of boys. This meant that these boys developed a permanent defective reproductive system resulting from a lack of function of the testes often accompanied by lack of sexual development and premature menopause. Those treated with hPG fell into two categories: those who were treated as ‘approved’ patients as part of an official program, and unrecorded numbers who were treated in the same way, using the same hPG, by medical practitioners who did not officially record details of patients they treated. These are referred to as ‘unapproved’.

The Allars inquiry established by this House to investigate the operation of the Australian Human Pituitary Hormones Program, conducted by Associate Professor of Law, Margaret Allars, is to be commended for its investigative work in relation to establishing the link between hPG and Creutzfeldt-Jakob disease and its recommendations to assist recipients, including compensation.

However, as the Allars inquiry states, the departmental database records 188 unapproved recipients, but only 28 per cent of those were able to be traced. The reality is that there is a high probability that there are many hundreds more than the recorded 188 unapproved recipients. As was stated in evidence in the Allars inquiry:

*Some doctors have come clean and told the department, others haven’t. This is why there are bound to be a lot of unofficial people out there that doctors have treated like this.*

I am raising this issue tonight because Mr. Michael O’Meara, a constituent of mine, came to me seeking assistance in relation to hPG treatment he received as a boy. His treatment was unapproved, and as a result it has taken many years to access any information about this treatment. His search for information was reiterated by Professor Allars when she stated in her submission: ‘When recipients were asked at interview what they wanted from the government, the vast majority said they wanted factual information.’ They, like my constituent, need that vital information in order to understand why today, some 30 years after the initial treatment, they experience debilitating side effects that cause hardship in daily living and real anxiety about future prognosis. Those concerns go to the heart of this motion and underpin the reason I have brought these issues to the attention of the House.

We need to recognize that the many hundreds of unapproved male recipients like my constituent received the same treatment as those who were approved in receiving hPG treatment, that they suffer the same, if not worse, risks and side effects because they have been denied access to medical records and because they have been part of this hidden or non-existent list of unapproved recipients. They have never been included in any considerations, whether they be in counselling, appropriate treatment or financial compensation. Further, in spite of the Allars inquiry making a recommendation on further actions which government might take to identify people in Australia who received the pituitary derived hormones and to provide counseling and support to them, this has not happened.

I want to emphasize further that, following the Allars inquiry, the Senate community affairs committee reported on the CJD settlement offer that resulted from Allars. While the compensation is to be commended, neither the Allars inquiry nor the Senate committee acknowledged the other side effects of hPG treatment, which have resulted in castration, delayed puberty, induced puberty due to high
doses of testosterone or hypogonadism. The government accepted the Senate recommendation stating:

*That once it is established that a person did receive hPG or hGH from the AHPHP, the recipient’s status should be of no difference to that of approved recipients.*

I strongly commend that Senate committee for making that recommendation to government and government for accepting it. But the point is that, in accepting this recommendation in relation to a link to CJD with hPG recipients, this acceptance should also be extended to other life-debilitating and life-threatening side effects of hPG treatment.

Let me give the House an actual example that my constituent has given me permission to speak of. My constituent was treated with hPG as a boy of 10 years of age. This resulted initially in a spontaneous onset of full-blown puberty. As treatment doses and frequency were varied, he was effectively castrated, with his testes so damaged that puberty was then delayed to such an extent that he was treated with anabolic steroids to induce puberty. This experimental nature of hPG treatment was exposed by Dr Wes Whitten, reproductive physiologist and former assistant director of the then National Biological Standards Laboratory. When giving evidence to the Allars inquiry, he said,

*It was a shocking product; I can’t believe this had ever been marketed.*

As a result of hPG treatment my constituent, as an adult, some 30 years later suffers from hypogonadism and requires three operations per year to keep him alive and reduce these extremely debilitating side effects. Every four months he has to undergo testosterone implants because, without these, his [hormone](https://en.wikipedia.org/wiki/Endocrine_system) level replicates that of a man over the age of 100. Mr. O’Meara is just one of many hundreds treated with hPG who officially do not exist on any health department list and who suffer in silence.

I commend Mr. O’Meara for his courage in being prepared to come forward and to provide me with very personal details in order to highlight the plight of so many others like him who justly, I believe, must be included in any government response to the ongoing needs of those whether approved or unapproved for treatment.

In the same way that approved recipients who were treated with hPG became victims of CJD and were recognised as being in need of counselling and compensation in some instances, so too do all the unapproved recipients need recognition of the treatment they received. This means that the spirit of Allars and the Senate committee must not just be adhered to; they must be implemented. There is simply no discrimination in the suffering experienced by both the men and women who were subjected to this treatment, and certainly no discrimination and suffering between those men and women who were approved under specific programs or those who were not approved. All who received hPG treatment and have suffered as a result of that treatment need to be recognised and supported. I commend this motion to the House and I thank my colleagues who have agreed to speak to this motion.
I rise to support the statement of the honourable member for McEwen. For the record, I am speaking about hormone treatment that was derived from pituitary glands taken from people who had died and the people who were subsequently affected by that treatment. Over 2,100 Australians between 1960 and 1985—and some reports say 1967 because that was when the official program started but it was actually between 1960 and 1985—were treated with such for infertility in women and short stature in children, particularly boys and young men, the particular focus of the member for McEwen’s statement.

I did have a chance today to have a look at the 800-page Allars inquiry report, which I could only look at very briefly, and I know if I was able to read it I would be much better informed on this. Also I did have a look at some other documents in the Senate inquiry to which the honourable member for McEwen referred. What happened was an absolute blight on our medical history. What happened to individuals in the community and to families and people who are still feeling the impact of that today was the result of systemic failure.

In speaking in support of the spirit of the statement and from the research that I have done, and when I looked at the Senate committee report that was looking at the CJD, the Creutzfeldt-Jakob disease settlement offer where it outlined all of the findings, it is obvious that there was an absolute systemic failure on the part of all agencies, groups and everybody else involved with it who had some oversight. These are the agencies that we the public, the community, look to for trust and we were badly let down during this period. The Senate inquiry report also said that it started some 30 years ago—but 30 years ago we still had knowledge of things like this. Also, what I have read leads me to believe that there was knowledge about the hormone growth treatment that should have led us to different conclusions and different oversight.

I should also state here that the Allars inquiry terms of reference were not concerned directly with the young men and the boys who received that hormone treatment. They were not the main targets. The inquiry really came out of the four cases of the women who we thought had the Creutzfeldt-Jakob disease. That prompted the inquiry. The report, however, speaks of those young Australians who received the growth hormones via the Australian Human Pituitary Hormone Program, because that was the program under which they received it, whether they were approved or unapproved, official or unofficial. In that sense, understanding the Allas inquiry and then the Senate report is apt and it is not analogous to use it as the primary response for this debate.

There are a number of key findings and conclusions that I found to be very alarming and they were repeated in the Senate inquiry. It concluded that the history of the listing of the hormones was one of circumvention of the PBAC and direct dealings between various agencies, the Director-General of Health and the minister. It said the testing by the NBSL itself was of great concern, and on the guidelines it said:

*The distribution of hormones under s.100 of the National Health Act appears to have been regarded by PBAC as a vehicle for delegating to the expert committees its normal function.*

That was something that really should not have been delegated on. On the use of section 100 it said:
... it was sought to create a role for the expert committees which would be responsible for approving patients for treatment.

Those patients were let down. It went on to say:

_It was an improper purpose and the Minister’s decision to list the hormones was an abuse of the power under s.100._

The last finding in this particular section talks about the role of the government decision makers and outlines a litany of tragedy of the medical history at that time. The Allars inquiry investigation, looking particularly at the Human Pituitary Advisory Committee and its subcommittees, exposed many issues of concern. The concerns were grouped under headings, and in some ways the headings themselves are sui generis.

The heading ‘research allocations’ talks about how some research allocations were allocated without the proper scrutiny and processes in place. Then it talks about ethical considerations and how various subcommittees failed to have regard to ethical considerations in a number of matters including the approval of the use of out of date hPG for ovarian stimulation tests in spite of disclaimers from CSL of their responsibility and failure to adequately sanction practitioners who failed to forward treatment sheets or failed to return hormones when their participation in the program was suspended. Then it talks about conflict of interest, which is another heading that is self-evident. Under the heading ‘knowledge of CJD’ it says that HPAC failed to respond appropriately to the knowledge of the risk and then it talks about exclusions in the regulatory role and the failures there. In the Senate inquiry report at 7.108 it says:

_The Committee considers that there is evidence to suggest that treatment under the AHPHP was of a more experimental nature than has previously been suggested._

That is very alarming in itself because, before we can actually know the impact some medical treatment is going to have, there has to be a period where it is used. From my reading of it—and I am not an expert in it—it was being used as a treatment to correct some medical problems but we were not told it was experimental. Everything I have read to date leads me to the conclusion that it clearly was experimental. I found that very worrying when I read it.

The other matter is unapproved recipients. I have come to the conclusion that the unapproved recipients seem to be harder to trace than the approved recipients for a whole range of reasons, as the honourable member for McEwen has already outlined to the chamber. But that should not stop them being traced. If something is the right thing to do, the fact that it is hard to do need not stop us from doing it. They do have to be traced.

In conclusion, it was particularly young men and boys—not exclusively so; there were some girls—who received some of this treatment. In our society, short stature might not be seen as a medical condition but it is seen as not being quite acceptable. As a person who is what I consider to be short—I am about 150 centimetres—I know what it is like to be little but I am a woman and I was always the little girl at school. Boys were treated very differently. Often in our society, with girls and slimming, there are a whole range of cosmetic things that impact on us psychologically where it is recommended to us that we treat these conditions medically. We have to change how we respond to people in our society with different sorts of looks. So it seems even sadder that some of those drugs were given to people,
particularly to young men and boys, and some girls, just because they were short. Listening to what
the honourable member was saying about the impact that has had on constituents in her area causes
me some distress because, yes, I have read about it, but she is obviously interacting with people who
have been affected. I give my support to the resolution. (Time expired)

I thank the member for McEwen for drawing the House's attention to the male recipients of growth
hormone between 1960 and the mid-1980s. In the mid-1950s scientists learnt how to extract human
growth hormone from the pituitary glands of cadavers. This hormone was injected into children of short
stature, increasing their height. Professor Allars’ inquiry demonstrated, unfortunately, a failure to
adequately protect public safety in relation to the Australian Human Pituitary Hormone Program,
AHPHP. There was evidence of failures in the production of product, including the collection of pituitary
glands; failures in supervision of the product and programs by government agencies, including the
health department, the National Biological Standards Laboratory and the Human Pituitary Advisory
Committee, or HPAC; and failures of appropriate action undertaken by the department following
suspension of the program in 1985. There were inadequacies in tracing the recipients, the information
provided, the epidemiological studies, and blood and organ donation.

Around 2,100 Australians were treated with human pituitary hormone under AHPHP, which ran in
Australia from 1967 until 1985. This program treated approximately 1,570 women and about 60 men
for infertility with human pituitary Gonadotrophin and approximately 660 children for short stature with
human growth hormone. Five Australians have developed and died from Creutzfeldt-Jakob disease, or
CJD, as a result of receiving human pituitary hormones. The program was suspended in 1985. Twenty-
two years ago, genetically modified growth hormone became available and side effects with this
hormone are rare. There is certainly no risk of CJD.

CJD is one of the transmissible spongiform encephalopathies. CJD was first described as a disease in
1920 and knowledge of CJD grew from the late 1960s as research was conducted into other spongiform
encephalopathies including kuru, an encephalopathy associated with ritual endocannibalism of the Fore
tribe in the remote highlands of New Guinea.

In 1968, transmissibility of CJD by inoculation of chimpanzee brains was reported. The first iatrogenic
person-to-person transmission by corneal transplant was reported in 1974. In the same year, warnings
appeared in the literature regarding the need for special precautions beyond routine sterilisation
procedures. In 1976, UK scientist Dr A Dickinson expressed concerns about the possibility of CJD
contamination of growth hormone produced in the UK.

Human-to-human transmission of CJD and other spongiform encephalopathies is now limited to cases
of accidental transplantation of an organ from a diseased person or in parenteral exposure to CJD
tissues through contaminated instruments, and in variant CJD transmission may be possible by blood
transfusion. Bovine spongiform encephalopathy, BSE, or mad cow disease, was probably caused by
dietary supplementation of cattle with processed organs from sheep with scrapie. People eating
infected cattle can become infected themselves. In all spongiform encephalopathies there is the
presence of a protease-resistant pathogenic form as an endogenous protein or prion in the brains of all
infected species. Deformed prions corrupt other brain proteins that aggregate and expand, recruiting
more proteins forming insoluble deposits that injure neurons and neuroglia. Neuroglia is the glue or
supporting tissue for the neurons and when lost causes the holes of spongiform encephalopathy.

The disease has a long incubation period of typically many months to years. When it manifests itself,
the dementia however progresses rapidly, unlike Alzheimer’s, which is slower. No single test other than
brain biopsy can confirm CJD and this is not easy, so examination of the cerebral spinal fluid along with
electroencephalography and MRI help confirm the diagnosis. We have no proven anti-prion drug or
vaccine so our males deserve the same compensation as our females.

I start my speech by saying that while listening to the member for McEwen one could not be other than
moved by hearing the personal story that came from one of her constituents. Such personal stories put
faces to these sorts of problems and make debates more than just talking about facts and figures. I
commend the member for bringing this motion on hormone treatment before us this evening.

This motion recalls a very unfortunate period in Australia’s medical history. Between 1960 and 1985
several thousand Australians receive hormones derived from pituitary glands taken from people who
had passed away. The hormones were used to treat children with growth problems and to assist in
treating infertile women. In 1985 a link between cardaveric derived hormones and CJD was recognised,
and the use of cardaveric derived hormones was stopped. Synthetic human growth hormone, which
was developed in the early 1980s, and follicle-stimulating hormones derived in other ways then came
into widespread use. A number of Australian recipients of pituitary hormones died from CJD in the late
1980s and early 1990s. The last recipient to die from CJD did so in 1991.

In May 1993, the then government asked Professor Margaret Allars from the University of Sydney to
carry out an independent inquiry into the use of human pituitary derived hormones in Australia and
CJD. In responding to the findings of the inquiry, the government, in November 1994, announced a
number of programs including funding for ongoing counselling and support services for human pituitary
hormone recipients and their families, funding for the medical and other care needs of human pituitary
hormone recipients who had contracted CJD, funding for commissioned research in Australia to assist
in developing a diagnostic test and treatment for the disease and for further epidemiology research,
and funding for continued information activities including a free 1800 number, medical advice and HPH
Newsletter.
The government subsequently made a settlement offer to recipients which included compensation for any psychiatric shock suffered by the recipients, as they were told that they were at increased risk of contracting CJD. The settlement offer was examined by a Senate committee of inquiry which reported in late 1997. One of the Senate committee’s recommendations was:

... the Department allocate resources to tracing unapproved recipients of human-derived pituitary hormones.

In response, the government, in March 1998, noted that the then Department of Health and Family Services was investigating strategies to identify unapproved recipients of the hormones and to trace the remaining recipients. The government noted that information about unapproved recipients was only available in the records of doctors who had been providing treatment under the program and that the department would need to contact each surviving treating doctor, requesting their further assistance in identifying unapproved recipients. I understand that this work was carried and that, as far as the department has been able to determine, 96 per cent of those patients have been traced. All patients, both approved and unapproved, were given an information package about the compensation available and were invited to apply for compensation for psychiatric shock if they believed they met the criteria. Two hundred and sixty-five recipients applied and $3 million was distributed to them. There was no distinction between male and female recipients and between unapproved and approved recipients in the compensation that had been made available—and that is a good thing.

The pituitary hormone trust account established in 1994 remains with a balance of almost $4 million. While the counselling services funded from the account were wound down in 2005, two years later than recommended by Professor Allars, pituitary hormone recipients can still access funding by contacting the Department of Health and Ageing, and that is something they should look at.

I think perhaps the saddest aspect is that this treatment went on for 25 years. Often I think with medical science we rush for the miracle cure too quickly; we do not spend the time and the research that are required to make sure that these products, these new methods, are safe. It is absolutely vital that in the future we do not go down this same path again and have the same sorts of very sad speeches being made in this place and around the country because we have rushed to a cure that turns out not to be a cure but an absolute curse. I commend the motion.