# ADDITIONAL SUBMISSION – DATED AUGUST 14, 2024 CHIROPRACTIC CARE OF CHILDREN UNDER 12 YEARS OF AGE

Lodged by Patrons of Chiropractic Science Inc. (PCS)

#### Introduction:

The decision to reinstate the restriction appears to have been based on two key elements:

- 1. Potential for harm to this group of patients: The Victorian Health Minister initiated an independent investigation via the Safer Care Victoria (SCV) Review, later promoting the restrictions. This Minister in announcing the SCV Review stated on May 19, 2019: "now it is time for parents who have experienced the dangerous practice of child spinal manipulation to have a say and share their story" and "we won't rest until babies are protected from practices we know to be harmful, and that we can be sure children under 12 are not being exposed to harm". (1) These very public, biased statements, clearly called for parents and guardians to make submissions to describe the harm and lack of benefit they experienced following chiropractic care. Disturbingly, how did this Minister come to believe these practices were harmful, as she had no evidence to support this claim? The SCV Review also provided the perfect opportunity for the medical profession, who has for the last century denigrated, attacked and lied about the chiropractic profession (seen as a competitor), to produce the 100's of cases of harm they persistently indicate exist.
- 2. <u>No evidence of benefit</u>: This was the Federal Health Minister's public statement on June 18, 2024: "*parents can have confidence that this practice has no evidence to support its efficacy*": transcript The Hon Mark Butler MP (2).

#### PCS will now address these two specific points:

#### 1 Evidence of harm

The public call by Minister Jenny Mikakos for submissions from both the public and professional groups to provide evidence of harm resulting from chiropractic care of children under 12 years of age in Australia **failed to generate a single valid case of harm**.

While PCS abhors use of the two YouTube videos released by chiropractors 2016 and 2018, that prompted the outcry, they did not demonstrate harm. They actually confirmed benefit, with patient/parent satisfaction confirmation of treatment and outcome. A third case from 2013 has been persistently raised by the medical lobby, citing possible fracture of a cervical vertebra of a 4 month infant following a chiropractic adjustment. This case was later dismissed. The paediatrician who identified what he thought was a fracture was later proven to be a congenital non-ossification (bilateral pedicle spondylolysis) of the C2 vertebra by expert radiologists. The child's father had a similar congenital anomaly. No other cases of harm were identified in Australia by registered Australian chiropractors. Only three cases of serious harm by practitioners were identified outside of Australia, one of these cases involved death of a 3 month old infant following treatment by a physiotherapist.

The professional indemnity insurers, the most reliable measure of such incidents of harm, failed to identify a single claim of harm. SCV Report states "*that while no cases of harm were identified, spinal manipulation is not wholly without risk*". (*3*) What the report should have noted, this perceived risk is amplified when undertaken by poorly trained practitioners, such as a physiotherapist. Additionally, manipulation is more associated with general mobilisation techniques that are utilised by osteopaths, physiotherapists and some medical practitioners, but not used by chiropractors, particularly when treating children. Such mobilisation techniques may move a joint beyond its physiological range of motion (ROM).

The important factor to consider is there very few activities or situations that are entirely without risk. The risk of a lightning strike is 1:1,000,000, or the Australian risk of dying in a motor vehicle accident in 2022 was 1:22,000. The risk of dying or suffering harm in Australia

as a result of medical treatment error, including receiving incorrect prescription medication is rather high. It is estimated over 18,000 people die, and over 50,000 suffer permanent serious harm each year in Australia. (4,5,6) Around 90% of Australians attend a medical practitioner each year; ~24.5 million people. Given the data confirms approximately 68,000 people either die or suffer serious harm from medical errors, this is a gross risk of harm for each patient attending for medical treatment in the order of **1:360**.

We suggest the Minister compares the risk of chiropractic care of children, that reported no evidence of harm in a patient population under 18 years of age. An estimated 30,000 children attend a chiropractor each week, or 1.5 million paediatric treatments a year. (7) The annual risk to children arising from chiropractic care appears to be **0:1,500,000** treatments.

A fundamental factor exists, which is clearly the reason for the total lack of evidence of harm (evidence being the key element the Health Ministers claim to desire). That is a chiropractor, when treating a child's spine, does not manipulate under the definition given in the National Law, which was the basic assumption within the SCV Report. Here, spinal manipulation is defined as 'being characterised by a high velocity, low amplitude (HV-LA) thrust beyond the physiological range of motion'. What each party to this ongoing inquiry and issue seems to be missing is that the specific correction made by a qualified chiropractor is an adjustment, very specific in nature, not a manipulation as defined, particularly for an infant or child.

At least three experts have published peer-reviewed, indexed critiques of this definition misunderstanding. Manipulation is defined by most parties as extending the joint by separating, or gapping, the two articular surfaces, where the force is directed vertically to these articular surfaces. To explain the distinction would require a lengthy dissertation, but PCS is happy to provide this material if requested.

The distinction of 'adjustment' has two critical differences to the spinal manipulation definition presented by the SCV Report and National Law:

1. Where a specific adjustment to a child's vertebra is deemed necessary, **the thrust utilised for a young child is not HV-LA, it must be low velocity, low amplitude (LV-LA)**. A child's vertebra requires minimal depth of setting to return the segment back into its normal physiological ROM, therefore the velocity of thrust must also be low. It is also preferable that such corrective thrust is delivered by hand so the practitioner can sense feedback from the anatomical structure within the patient to further modify the adjustment. Additionally, the thrust should not incorporate Y-Axis rotation of the vertebra or spine, particularly in the cervical region.

Such guidelines are imbedded in the accredited chiropractic university training programs, and again, are the key reasons for the total lack of identified injury.

Alternatively, at times, the adjustment may not be a LV-LA setting, it may involve a very gentle digital pressure (no more finger tip pressure than what you could tolerate on your eyeball) on the affected vertebra that triggers an afferent proprioceptive response into the cortex of the brain, which then results in efferent feedback to the site of injury that stabilises the associated structures and function. These responses and pathways are well researched and evidence of this can also be provided upon request.

2. The second critical element to understand is the direction of this adjusting force never extends the joint beyond its physiological limits. In fact, the chiropractic correction of a compromised vertebra should not be directed towards these extents. Due to the joint fixation dysfunction, neurological impacts and interpreted juxta-positioning ("subluxation"), any force is always directed back towards the neutral position for that articulation. It is more accurate to describe the adjustment as being specifically designed to return a compromised vertebral segment towards or back into its neutral position within the normal physiological range of motion. Nor is the articulation extended in a vertical direction to separate the articular surfaces.

These are the most important reasons why there was no evidence of harm. Naturally, PCS and its members support diligent monitoring of the practises of every practitioner by AHPRA, and in the case of chiropractors, the CBA to ensure the adjusting standards noted in points 1 and 2 above are maintained. In this way, the absence of any future cases of harm to children under 12 years of age receiving chiropractic care can be assured.

- 2 Evidence of efficacy
- a) <u>Clinical procedures evidence standards:</u>

PCS has previously explained the difficulty that all clinical applications face in developing what you might regard as Level I, II or III-1 strong evidence (see Table A), that generally arise from random controlled (double blinded) trials (RCT).

Both chiropractic, the medical surgical and clinical branches (as well as many general medical practise activities) fail to offer such standards of evidence for the vast majority of their procedures. This largely relates to ethical and methodological reasons. To blind a group of patients and deny care is both discriminatory and in breach of our respective oaths of care. For example, it is not ethical to perform an RCT on a surgical procedure that has already been used extensively and widely accepted by surgeons. Such procedures are often based on acceptance of expert opinion and some case studies demonstrating a level of outcome efficacy.

Similarly, it is not ethical to perform an RCT for a chiropractic procedure that has already been used extensively, safely and widely accepted by chiropractors for the past 100+ years, but also supported by expert opinion and some case studies demonstrating a level of efficacy. Further, a placebo or blinding can only ethically be used when there is no known preferred treatment. We know this because numerous, proposed research projects have been rejected by university ethics committees.

For this reason, development of research and high quality evidence is challenging, but more so for the chiropractic profession, which does not operate in public hospitals or clinics. Critically, chiropractic fails to attract government or institutional funding.

Australian medical research in 2023 exceeded A\$10 billion, of which over A\$2 billion was funded by government grants, as indicated in the Table 1 below.

NHMRC Funding	\$946 million
ARC Funding contribution to HMR (10%)	\$81 million
Research Block Grants contribution to HMR (35%)	\$700 million
MRFF	\$650 million
Total	\$2,377 million

 Table 1: Government medical research funding – 2023/2024

# b) <u>Standard of evidence of medical practices:</u>

However, regardless of this significant medical research funding pool (which excludes pharmaceutical research and testing), Ebell et al 2017 findings published in the British Medical Journal, (8) confirm that in primary care-oriented medical treatment, only 18% of recommendations were based on consistent, high-quality patient-oriented evidence (class A), while over half were based on expert opinion, usual historic care or disease-oriented evidence (class B). Clinical categories with the most Class A recommendations were pregnancy and childbirth, cardiovascular, and psychiatric. Categories with the least evidence were haematological, musculoskeletal and rheumatological, poisoning and toxicity.

This study confirmed that primary care physicians and Australian Health Ministers need to be aware that only a **minority** of medical treatment recommendations are based on high-quality, patient-oriented evidence.

Further, a detailed systematic review by Howick et al of 1,567 medical interventions into the extent of high quality evidence tested by Cochrane Reviews was conducted in 2022. (9) This confirmed that 94% of interventions were not supported by high quality evidence. This study also confirmed that more than half the interventions are supported by weak evidence, such as expert opinion and case studies. The study concluded that more than 9 in 10 healthcare interventions studied within recent Cochrane Reviews were not supported by high-quality evidence, and notably, harms were significantly under-reported:

## c) <u>Access to funding for chiropractic research and search parameters:</u>

Conversely, chiropractic research received no government or university funding in 2023. In fact, PCS cannot confirm any evidence of direct government funding for chiropractic research, despite recommendations for modest research funding by all previous Australian and New Zealand inquiries and reviews since 1975, including SCV (2019). Why is a registered health provider unable to access government research funding?

Over the past decade, approximately A\$3 million has been raised within the chiropractic profession for research funding by organisations such as the Australian Chiropractic Association, the Australian Spinal Research Foundation and PCS. While this funding is a credit to such a small profession, the sums required to conduct even a couple of RCT's would consume a significant majority of such modest funds, and apparently for such research to be "recognised" it could only focus on a single presentation subgroup, such as colic. Research now being considered by PCS to conduct a <u>single laboratory research project</u> into neurological pathways and responses involved with the subluxation complex and its correction is likely to exceed A\$2.5 million. Compounding the research challenge for all modes of health care research into the paediatric patient is such research is complex, costly and rare.

Another Cochrane Review into evidence of benefit, apparently undertaken following the SCV Review, would again be likely flawed, as searches for chiropractic studies would have focussed on the similar medical and traditional scientific journals, and their related search platforms, such as PubMed, AMED or Scopus, but failed to search other more relevant chiropractic publications. Cochrane seems happy to exclude chiropractic expert opinion or case study data, <u>similar evidence</u> that many practises within the medical profession rely upon, and still regarded as evidence in the accepted evidence hierarchy (see Table A below).

While some chiropractic studies are on occasions published and referenced in such platforms, they only form a fraction of the published works that feed into the many specific chiropractic journals, including but not limited to Australian publications like the Asia Pacific Chiropractic

Journal, the Chiropractic journal of Australia, the International Journal for Practising Chiropractors, and the global Journal of Clinical Chiropractic Pediatrics.

Table A: classifications of evidence



PCS requests the Health Ministers Meeting (HMM) treat the standards for available paediatric evidence for each intervention in the same manner for both the chiropractic and medical professions. In reality, they are both weak by EBM standards, particularly in paediatrics.

For example, we could not find a single high quality or RCT medical study related to effective medical treatment for enuresis (bed wetting). There are summary papers, such as by Rincon et al (10) or Tsuji (11), that described this debilitating disease, but no EBM treatment was offered, only a statements that treatment of this common condition can be tailored according to the patient's underlying cause, for which the papers vaguely suggest "is considered a multifactorial entity with a strong genetic component that may be influenced by comorbidities and immaturity of the central nervous system bladder control mechanisms". "Suggested" treatments ranged lifestyle guidance and limitation of fluid intake to "aggressive treatments" such as prescription oral desmopressin, an antidiuretic hormone preparation, or alarm therapy.

Another example of the lack of quality evidence is medical treatment for Infantile Colic. The 2018 study/review by Zeevenhooven et al (12) accurately describes medical diagnostic methods and treatments, including parental education, behavioural strategies, dietary, pharmacological interventions, but points out that owing to a lack of large, high-quality randomized controlled trials, none of these therapies can be strongly recommended, yet they are all utilised based on expert opinion and some case studies.

The extensive review by Ellwood et al, (13) compares a number of interventions, including manual therapy/chiropractic, simethicone (medication to reduce stomach gas, but with side effects including allergies and breathing difficulties), probiotics, proton pump inhibitors. This study found there was evidence for the treatment of infantile colic using probiotics, particularly *Lactobacillus reuteri* for breastfed infants, followed by weaker but favourable evidence for manual therapy indicated by crying time. Both forms of treatment were found to carry a low risk of serious adverse events.

Numerous chiropractic case and case series studies offer a specific, effective treatment approaches that positively impact both enuresis and colic, yet apparently this treatment is to be denied due to weak evidence. Does this mean the medical profession must also now cease treating enuresis and colic given their evidence is also technically weak?

The indisputable fact remains, in the real world of health care, all providers (medical and chiropractic) must commit to giving the best and safest health care possible with an insufficient evidence base. As Dr Joyce Miller DC, Ph.D, (14) paediatric author and lecturer (AECC University, UK) recently noted, providing safe and effective care in gray areas with insufficient evidence should be applauded, not denigrated, censured or restricted.

## d) <u>How is benefit measured:</u>

It has long been accepted that the optimal way to gauge benefit of intervention is to use some of the protocols established by Prof Gordon Waddell CBE, DSC, MD, FRCS. (15) He noted that the medical model is simplistic, incorrectly assumes that all illness has a single cause (disease), that treating the disease will restore health, and fails to take account of the personal and social dimensions of sickness and disability.

Prof Waddell was credited for the development of the biopsychosocial model of medical care, which is applicable to all forms of recognised health care. This widely accepted model considers evidence that that represents positive outcomes and the sense of well-being for the patient, where the ultimate goal of healthcare is to care for people who are ill and to relieve human suffering. Chiropractic care and success is a part of this healthcare objective, even for young children. The SCV Report confirmed a 98% (21,474 kids) well-being improvement.

# e) <u>Chiropractic does have evidence of benefit:</u>

The evidence matter each Health Minister must carefully consider is not only the expectations for challenging high quality studies, that clearly both medicine and chiropractic fail to adequately meet, but also consider the weaker evidence offered by expert opinion, case and case series studies, that form the bulk of clinical application efficacy consideration. For example, PCS has previously provided a partial list of some 40 studies related to infant colic. Further, the 2016 YouTube video and its published case study of an infant being adjusted following spinal injury resulting from a medical resuscitation procedure (necessary but very confronting), showed that a single chiropractic adjustment (also apparently somewhat confronting) immediately resolved the severe distress and colic symptoms.

# We draw your attention to the accompanying video download link so you can understand context for this specific case (16). (*Video virus and malware protection by Google Drive*)

In this specific case, the difficult delivery, example of the confronting standard resuscitation procedure you will observe in the supplied video, the two-week period of infant and parental distress that followed, the chiropractic treatment and the immediate positive well-being outcome were all confirmed by the parents via the CARE Case Study patient acknowledgement protocols. While PCS recognises this is an N=1 case study, it still forms undeniable evidence, as do many of the other case and case series studies discussing colic.

PCS noted a statement in the SCV Report, page 24, that the "The consumer representatives were particularly surprised at the lack of evidence" following receipt of the extremely limited, selective and restrictive search conducted by Cochrane. It was unfortunate that these consumer representatives were not shown for example some of the ~40 colic studies. While most of these related to "weaker evidence" case studies, in a similar manner as many outcomes identified by medical case studies that often prompt further research, such positive results should be sufficient to also motivate government funding commitments for chiropractic research in Australia. To date, again, this has not been the case for chiropractic care.

While both medicine and chiropractic must, within ethical boundaries, continue to develop higher quality evidence, is the answer to cease or restrict each avenue of care for all health

professions until the perfect "high quality evidence" is generated for every procedure? Clearly, this possible, but extreme approach, would be a public health disaster.

# d) <u>SCV Report offers clear evidence of benefit:</u>

Ultimately, we can all agree the studies where the N value is 1, 5 or 10, regardless of the wellbeing outcomes, may require further research. However, PCS directs you to the findings of a recent, much larger study, which was actually conducted and analysed independently of the chiropractic profession.

We ask all Health Ministers to actually consider the findings of the 2019 SCV Review. PCS understands that while this report has been tabled to the HMM, to date you seem reluctant to accept it. Does this reluctance relate to the high satisfaction rating, or lack of evidence of harm? PCS understands this review was primarily initiated to establish evidence of harm and negative experiences. However, the results actually offer clear evidence of benefit and positive well-being outcomes. Importantly, this review actually represents a focussed outcome and retrospective cohort study where the N value = 21,824.

The SCV Review was a totally independent, government-funded inquiry that called for parents to describe the harm and lack of success arising from their child's visit to a chiropractor. The questions appeared to create bias, but regardless of this fundamental issue, 98% of the N=21,824 respondents reported the child's complaint either improved or resolved: **Benefit!** 

The main presentations were posture (31.7%), Colic (28.7%), neck pain (23.5%), breastfeeding issues (22.6%), back pain (21.9% and headaches (14.9%), walking problems (10.8%), special needs and ADHD (10.5%), crawling issues (8.7%), bedwetting-enuresis (8.3%), Asthma (7%), as noted in Table 2 below.

The SCV Review effectively confirmed a 98% improvement or resolution of these and other conditions that were validly reported by the public. This by any standard is evidence of benefit, and certainly positively contributed to an improved sense of well-being for both patient and parents. The statement that chiropractic "*has no evidence to support its efficacy*" is simply false and misleading.



Table 2: SCV respondent findings of conditions presenting to chiropractors

Many statisticians concur that a sample size of 100 is the minimum you need for meaningful results. Where the population is smaller than 100, one should aim to survey all of the members. The same source states that the maximum number of respondents should be 10% of the target population, but it should not exceed 1000 due to cost with little improvement in accuracy (*17*). SCV Data: N=21,824, but the Ernst & Young (EY Sweeney) randomly sampled ~10% of all public responses; N = 3265, with the expectation that the margin of error would be +/- 1.7% with a 95% confidence in the findings. Ernst & Young did not believe a larger sample would significantly impact any errors in the findings, which are clearly valid.

SCV received 29,054 valid submissions, where 21,824 were from parents and guardians that had consulted with a chiropractor for a child under 12 years of age within the past 10 years. 54.5% of these respondents (N=11,894) related to care of an infant under the age of 3 months. 73.1% of the respondents (N=15,953) related to care of an infant under the age of 2 years. This number of data points provides an excellent sample size for the age groups of greatest apparent concern to the HMM body.

A far more telling finding for the necessity to maintain chiropractic care of infants and children under 12 years of age is the SCV data that confirmed that of the 21,824 parent responses, 17,622 cases noted they had previously consulted with other health professionals, most probably with little or no resolution, as a patient rarely consults with another practitioner or healing art if the presentation is resolved in the first instance.

These other health professionals included: 68.9% had attended a medical practitioner, 43.9% attended a maternal and child health care nurse, 18.2% had attended a medical specialist, and 14% attended a physiotherapist; all costly but apparently ineffective interventions.

# Importantly, chiropractic care improved or resolved 98% of the presentations at minimal cost to the public purse.

Clearly, chiropractic care resulted in improved outcomes and benefit for 98% of those that received treatment, effectively helping these children, where in many cases the medical model of health care had failed. Could this be a factor for the persistent complaints by the medical lobby?

## **Conclusion:**

Two fundamental questions must be addressed and fully substantiated by the HMM to ethically and legally maintain the reinstated restrictions: **that there is evidence of harm** and **there is no evidence of benefit?** 

# <u>PCS contends that there is no evidence of harm in Australia and there is evidence of benefit, albeit perhaps "technically weak" at this point. Unwittingly, the Victorian Minister for Health in 2019 may have provided the strongest statistical evidence of benefit resulting from chiropractic paediatric care in Australia to date.</u>

Australian chiropractors graduate from accredited Australian universities with specific skills to also treat children. These include training in physical examination, including the neurological and orthopaedic screening tests required to in part recognise when a referral to other specialties may be required, and numerous gentle, but specific treatment techniques for a variety of presentations. This standard and effectiveness of university training, which has been accredited by TEQSA and CCEA as directed by government, is clearly indicative of the safety incorporated into chiropractic care and is the reason for the absence of evidence of harm. Government's designated accrediting agencies should be congratulated.

The New Zealand Commission of Inquiry into chiropractic in 1979 made this statement that should form a significant component of your consideration; 'What chiropractors have done has been to develop the art of spinal functional analysis and adjustment to a degree with which the medical profession as a whole cannot compete. They have developed a range of techniques and skills which few outside the chiropractic profession have been able to master.'

The SCV Report is strong evidence that the profession can competently self-manage itself. It should not only be about evidence of clinical effectiveness, as even medicine admits that generally, the evidence bar is low for them. The critical evidence demonstrated by lack of harm is that through self-regulation within AHPRA, the chiropractic profession has managed itself to deliver to all Australians remarkably safe care across the full lifespan of patients, including the under 2 years age group, with positive concomitant results over a variety of presentations.

PCS, like all chiropractic professional organisations and associations, has the primary objective to ensure safe and effective care to the thousands of Australian parents and their children, who have the trust to seek chiropractic care for many health complaints. Unfortunately, on rare occasions, an individual practitioner may breach ethical and care standards. Such breaches exist in every aspect of health care, including medicine.

We again remind the HMM of the cluster of many avoidable Bacchus Marsh Hospital infants deaths (between 2008 and 2015) that arose from a combination of malpractice and misconduct. Not just harm, actual deaths. This is not an isolated incident, as in 2018 a 4 day old infant died in Sunshine Hospital. Just last week we hear of another Coroners reporting of an infant death in 2021 at the Wangaratta Hospital and another at the Geelong University Hospital in 2022, each of these deaths caused by similar preventable causes. However, in the isolated cases of such failures and breaches, the individual practitioner must be censured or disciplined, not the entire dedicated profession.

Accordingly, in addition to the sensible informed consent and patient education requirements articulated within the SCV Report, PCS suggests the HMM includes the following standards for all registered health practitioners when treating children under 12 years of age:

- 1. Any adjustments to be delivered in a measured fashion taking into account the anatomical limitations and development of the vertebral segment and area of the spine being targeted;
- 2. To maintain registration, no chiropractor (or any other health practitioner) is to display via social media or personal advertising any videos of actual adjusting and care procedures undertaken in their respective practices;
- 3. To ensure each practising chiropractor remains fully aware of developing examination and care protocols for children, a component of the statutory continuing professional development (CPD) hours each year be dedicated to paediatric care to maintain registration;

PCS strongly supports the SCV Recommendation 5, and therefore requests that the Government budget and grant a modest amount compared to medical research funding of at least A\$25 million each year to recognised Chiropractic institutions and approved Chiropractic research charities so that the generation of new and classification of current evidence of efficacy can be elevated from weak to strong, as the HMM body requires.

PCS is working closely with all of the other chiropractic organisations active in Australia to resolve this matter. The profession will also reach out to the many thousands of parents that choose chiropractic care for their children, particularly when the various branches of medicine fail them. Many parents will be incensed, as our profession will be compelled to explain the reasons why Australian Health Ministers seem so heavily influenced by political medicine that

they are actually contemplating limiting the very care these parents have the right to seek, and clearly experience benefit.

Further, has the HMM even considered the fiscal benefits to government when the relatively high cost of ongoing medical care, that at times fails the public in many areas, is compared to the relative low cost resolutions offered by chiropractic care? In large outcome studies, parents report excellent clinical outcomes, and high rates of parent satisfaction. There is also evidence of cost-effectiveness. (18, 19, 20)

PCS presents this information to better inform you of the nature of both chiropractic technique and the level of evidence that is actually available for the vast majority of all clinical health care applications, both chiropractic and medicine. We look forward to your fair consideration of the points made in this additional submission and trust the unjustified restrictions can shortly be removed.

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