



INSTITUT C.D. HOWE INSTITUTE

COMMENTARY

NO. 541

Regulating Alternative Medicines: Disorder in the Borderlands

*With the use of alternative medicines increasing in Western countries, along with concerns about standards, an approach to regulating certain popular forms of these medicines is needed.
Regulation should be calibrated to the degree of risk entailed.*

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COMMENTARY No. 541
April 2019
HEALTH POLICY

\$12.00

ISBN 978-1-989483-03-9

ISSN 0824-8001 (print);

ISSN 1703-0765 (online)



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THE STUDY IN BRIEF

In many Western countries, the use of complementary and alternative medicines (CAMs) has been growing. Individuals in Western countries often use CAMs in conjunction with biomedicine (also referred to as allopathic or Western medicine), or sometimes choose to rely on CAMs as alternatives to biomedicine. In most contemporary Western societies, biomedicine is relatively strictly regulated, while regulation of CAMs reflects a much less settled regulatory landscape. With use of CAMs increasing and concerns about standards, an approach to regulating certain popular forms of CAMs is needed.

The central regulatory challenge is how to provide for patients' autonomy over their own treatment while addressing the core challenges of severe information asymmetries and negative externalities. Regulation of CAMs should be calibrated to the degree of risk entailed, especially where CAMs are promoted as substitutes for, rather than as complements to, biomedicine in treating potentially life-threatening health conditions.

C.D. Howe Institute Commentary© is a periodic analysis of, and commentary on, current public policy issues. Barry Norris and James Fleming edited the manuscript; Yang Zhao prepared it for publication. As with all Institute publications, the views expressed here are those of the author and do not necessarily reflect the opinions of the Institute's members or Board of Directors. Quotation with appropriate credit is permissible.

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The field of complementary and alternative medicines (CAMs) groups together a vast array of medical treatments such as homeopathy, chiropractic, osteopathy, naturopathy, Ayurveda, Siddha, Unani, traditional Chinese medicine, and spiritual therapies (Bodeker et al. 2005).

In many Western countries, the use of CAMs has been growing (Clarke et al. 2015; Crouch et al. 2001; EUROCAM 2014). For example, a 2016 study by the Fraser Institute concluded: “More than three-quarters of Canadians (79%) had used at least one complementary or alternative therapy sometime in their lives in 2016. This compares to 74% in 2006 and 73% in 1997” (Esmail 2017, ii).

Relative to many other product and service classes, health-related products and procedures often pose severe information asymmetry problems for consumers: most individuals lack the expertise to diagnose disease or choose appropriate medical treatments. Moreover, although a medical professional offers expertise in diagnosing or treating disease, the potential patient faces an information asymmetry in evaluating the quality of the practitioner’s services. The information asymmetry is aggravated when professionals misrepresent their skills or the benefits of their services (see, for example, Cohen 2018). Regulation can play a critical role in addressing these information asymmetries by establishing standards of practice that assure potential patients that a practitioner provides competent services.

Most Western countries, however, recognize fundamental rights around an individual’s security

of the person, including competent, patient-informed consent for treatment and the refusal of treatment.¹ The central regulatory challenge is how to balance the aim of enabling individual autonomy in selecting treatment while addressing information asymmetry problems. As well, once a regulatory regime is imposed, regulation might become a barrier to entry. Specifically, (1) the design of regulations might be “captured” by established practitioners who limit entry by other professionals; and (2) established practitioners might be averse to new approaches to practice – for example, new treatments or technologies.

Most Western societies strictly regulate biomedicine – both the medicines and medical practitioners. For example,

- many medications may be accessed only with a prescription from a licensed medical practitioner and must be dispensed by a licensed pharmacist;
- medications are available only after extensive clinical trials and approval by a government drug safety agency that evaluates scientific efficacy and the risk of negative side effects;
- non-prescription medicines must often be accompanied by warnings of potential side effects or prior vulnerable predispositions;
- entry to medical professions is restricted, and

We are indebted to Grant Bishop, Tom Closson, Sherman Cohn, Kevin Davis, Colleen Flood, Noel Semple, Carolyn Tuohy, John Wallenburg and anonymous reviewers for helpful comments on earlier drafts and to comments of participants at a University of Toronto Faculty Workshop, November 6, 2017, and a Health Policy Council meeting at the C.D. Howe Institute, November 21, 2018.

1 The discussion in this *Commentary* concerns non-dependent adults with the capacity to choose their own treatment. Issues of treatment for children and other dependents and for those with mental incapacity are largely beyond the scope of this study.

those practising without a licence are subject to criminal prosecution; and

- physicians, medical specialists, pharmacists, dentists and nurses must undertake rigorous training programs and meet accreditation requirements established by applicable professional bodies.

Many Western countries have delegated regulation to self-governing professional organizations. These organizations have responsibility for the ongoing integrity and competence of their members through disciplinary regimes and continuing education requirements (see Dewees, Trebilcock, and Duff 1996, 122–35). For medical practitioners, the primary emphasis is on input regulation, focusing on ensuring that practitioners meet minimum educational and training requirements to qualify and continue to practise. Relatively less focus is placed on output or outcome regulation, which is addressed through the disciplinary procedures of self-governing bodies and the tort system in cases of alleged medical malpractice or negligence or defective products.

For the regulation of CAM products (non-biomedical medicines) and practitioners, the regulatory landscape is much more unsettled, as we briefly review below.² We propose that the regulation of CAMs should be calibrated to the degree of risk entailed.³ Certain commentators object to the regulation of CAMs on the basis that regulation would give legitimacy to practices that many regard of questionable therapeutic value. Where CAM treatments could displace biomedical treatments, however, we suggest that there is a role

for tailored regulation to balance the public interest in protecting individuals from misrepresentations with respect for individual autonomy.

More specifically: if a particular CAM treatment is not harmful and is not marketed to displace biomedical treatments, government should not intervene and should not inhibit individuals from accessing products. However, where CAMs are promoted as a substitute for, rather than a complement to, biomedicine in treating serious biomedical health conditions, government should require a minimum standard of scientific efficacy and should use appropriate penalties to restrain representations of CAM treatments that do not meet that standard. Table 1 outlines how these principles would apply to regulate certain forms of CAMs. Governments should create appropriate institutional machinery to delineate the appropriate thresholds for risk and contextual tests for “minimum scientific efficacy.” We suggest governments convene CAM advisory councils to provide independent advice to government on regulation and, where required, the monitoring of compliance by practitioners.

MAJOR SCHOOLS OF CAMS AND THEIR REGULATION

Approaches to regulating CAM products and service providers differ widely across the six jurisdictions in our sample: the United States, Canada, the United Kingdom, Europe⁴, New Zealand and Australia. This diversity is highlighted

2 For a more detailed discussion and citations, see our longer paper by the same title (available from the authors).

3 Certain reviewers of this *Commentary* noted that “quality,” “risk” and even “scientific efficacy” are not “neutral” concepts and do not involve consistent, objective standards. We agree, and therefore recommend an institutional approach to provide government an independent perspective to delineate appropriate context-specific thresholds.

4 The 2012 CAMbrella study (see footnote 5) by Wiesene et al. has surveyed 39 European countries, which includes the United Kingdom, although in our tables we have reported on the United Kingdom separately.

Table 1: Regulatory Principles for Complementary and Alternative Medicines

| CAM Products and Procedures | Principle |
|---|--|
| CAM products and procedures that treat non-life threatening health conditions. | If treatment is not harmful, no government intervention. |
| CAM products and procedures that treat potentially life-threatening health conditions as a complement to biomedical products and procedures. | If treatment is not harmful, minimal government intervention to ensure that practitioners do not misrepresent therapeutic potential. |
| CAM products and procedures that treat potentially life-threatening health conditions as a substitute for biomedical products and procedures. | If treatment lacks minimum standard of proven scientific efficacy, it should be prohibited. |
| Source: Authors' compilation. | |

in a 2012 study⁵ (Wiesene et al. 2012) examining regulation of CAMs in 39 European countries. Here we discuss regulatory approaches to seven of the most common CAMs: naturopathy, homeopathy, chiropractic, osteopathy, acupuncture, traditional Chinese medicine and Western herbal medicine. For each, we provide a brief description and a table showing how each jurisdiction regulates the particular practice.

The three typical modes of regulation of CAMs are:

- *exclusive licensing regimes*, typically accompanied by government delegated self-regulation, which reserve certain fields of practice to licensed practitioners and render it illegal for unlicensed practitioners to practise in the reserved domains;
- *official certification*, which reserves certain titles to certified practitioners, typically under a government-delegated self-regulatory regime, but does not preclude uncertified practitioners from practising in the defined domains but under different designations; and

- *voluntary private certification regimes* administered by private professional associations (akin to private trademarks).

Naturopathy

Naturopathy seeks to prevent and cure illnesses by using materials that nature supplies. It promotes holistic healthcare by promoting a healthy lifestyle (WHO 2010, 3–4). To treat illnesses, naturopaths use an array of modalities, advising on nutrition and diet and prescribing botanical medicines and hydrotherapy, among many others (WHO 2010, 4).

The definition of naturopathy is controversial (Webb et al. 1977), with opinions differing as to whether it is distinct from or overlaps other forms of CAMs, particularly homeopathy (Ernst 2016, 293–4). The definition of naturopathy affects regulation – for example, whether to permit or promote the practice of homeopathy/acupuncture by licensed or certified naturopaths. For our

5 The study was undertaken by CAMbrella, a pan-European research network for complementary and alternative medicine. The research project was funded by the 7th Framework Programme of the European Commission. The research group consisted of 16 partner institutions from 12 European countries. It is asserted that the objective was to research CAMs, not to advocate them.

Table 2: Regulation of Naturopathy, Selected Jurisdictions

| Jurisdiction | Regulatory Approach |
|-------------------------------|---|
| Canada | <ul style="list-style-type: none"> Five provinces – British Columbia, Alberta, Saskatchewan, Manitoba and Ontario – statutorily regulate naturopathy, undertaken through a licensure regime. Unlicensed naturopaths are prohibited from practicing. Nova Scotia has enacted <i>The Naturopathic Doctors Act, 2008</i>. The act is limited in scope, the primary objective being to grant title protection for naturopathic doctors in Nova Scotia. |
| United States | <ul style="list-style-type: none"> 19 states statutorily regulate naturopathy, some through licensing (in these states, unlicensed naturopaths are prohibited from practising) and some through government-approved certification. Other states: voluntary, private certification. |
| United Kingdom | No statutory regulation; voluntary, private certification. |
| New Zealand | No statutory regulation; voluntary, private certification. |
| Australia | No statutory regulation; voluntary, private certification. |
| Europe | <ul style="list-style-type: none"> Of 39 countries, only 8 statutorily regulated as of 2012, some through a licensure regime and others through government-approved certification. Some countries categorize naturopathy as a “health profession.” Germany recognizes naturopathy as a “distinct therapeutic system” under the Code of Social Law (1998). In Switzerland, naturopaths fall under the category of “natural health practitioner,” a statutorily regulated profession. |
| Source: Authors’ compilation. | |

purposes, naturopathy is treated as distinct from homeopathy, given our aim of exploring how each of these is currently regulated, as shown in Table 2.⁶

Homeopathy

Homeopathy was developed by Samuel Hahnemann, a German physician in the 1790s (Bodeker et al. 2005; Porter 2002, 48; WHO 2010, 3–4). The foundational principle of homeopathy is “like cures like” (Loudon 2006). To treat an illness, homeopaths prescribe “minute doses of [potentized]

natural substances that in larger amounts would produce symptoms of the ailment” (Ernst 2016, 36–7, 225). These substances are intended to stimulate the body to fight the disease, unlike biomedicine, which fights the disease directly (Bodeker et al. 2005). A crucial difference between homeopathic medicines and natural remedy treatments such as naturopathy and Western herbal medicines is that the former are made by potentizing natural substances, while the latter often use plant extracts in their crude form.⁷ Multiple schools of thought have evolved within homeopathy. Some schools

6 For citations supporting the regulatory approaches described in this and subsequent tables in the *Commentary*, see our longer paper by the same title (available from the authors).

7 European Committee for Homeopathy, “Homeopathy – Got Questions? We’ve Got Answers!” available online at <https://homeopathyeurope.org/practice/f-a-q/>.

Table 3: Regulation of Homeopathy, Selected Jurisdictions

| Jurisdiction | Regulatory Approach |
|-------------------------------|--|
| Canada | <ul style="list-style-type: none"> Statutorily regulated only in Ontario through self-regulation via a certification regime, limiting the use of the title “homeopath” to certified practitioners. Other provinces: voluntary, private certification. |
| United States | Regulation varies across states. Typically, states include homeopathy under chiropractic, naturopathy and physical therapy. Some states limit homeopathy to medical professionals and other licensed health care professionals (e.g. chiropractors). |
| United Kingdom | <ul style="list-style-type: none"> Recognized as a distinct medical treatment system. Can be practised by doctors (biomedicine), non-medical practitioners who are voluntarily registered with professional associations, and others who choose not to be registered. Has established a self-regulatory registration system, and non-medically qualified homeopathy practitioners can register voluntarily with professional associations subject to meeting certain conditions. |
| New Zealand | No statutory regulation; voluntary, private certification. |
| Australia | No statutory regulation; voluntary, private certification. |
| Europe | <ul style="list-style-type: none"> Of 39 countries, statutorily regulated in 24 as of 2012. Recognized as a distinct medical treatment system in some countries, such as France and Germany. In others, falls under a more general category of alternative medicines, or is included under other CAM practices (similar to the United States). Some countries strictly control the qualifications needed to practise, others permit a range of practitioners to practise. For example, in Austria, France and Italy, only biomedical practitioners such as doctors and dentists can practise homeopathy. In Germany, doctors (of biomedicine) with additional qualification in homeopathy and <i>Heilpraktiker</i> can prescribe homeopathic medicines. <i>Heilpraktiker</i> are entitled to practise CAMs, including homeopathy, subject to passing certain examinations and being licensed. |
| Source: Authors’ compilation. | |

Table 4: Efficacy Requirements of Homeopathy, Canada and the United States

| Jurisdiction | Regulatory Approach |
|-------------------------------|---|
| Canada | <ul style="list-style-type: none"> Proof of efficacy is accepted if listed in homeopathic pharmacopeias, which may rely on historical use. The Natural Health Products Regulations (SOR/2003-196) require that homeopathic products be approved by Health Canada prior to being sold. However, a 2015 CBC investigation concluded that Health Canada issued licences and permitted marketing of natural health products (which includes homeopathic medicines) without requiring submission of any scientific evidence. |
| United States | <ul style="list-style-type: none"> Homeopathic medicines are regulated by the <i>Food, Drug, and Cosmetic Act</i>, but the Food and Drug Administration does not actively assess homeopathic medicines for their safety and efficacy. |
| Source: Authors’ compilation. | |

oppose certain principles espoused by other schools. Table 3 shows how homeopathy is regulated in our sample jurisdictions. As Table 4 shows, homeopathic medicines are typically not required to meet proof of efficacy to the same degree as is biomedicine.

Chiropractic

Chiropractic was developed by Daniel David Palmer, a Canadian-born storekeeper from Iowa. He treated his first patient in 1895, restoring the patient's hearing by adjusting his spine (Duffin 2010, 159–60; Porter 2002, 50). Palmer defined chiropractic as “a system of adjusting the segments of the spinal column by hand only, for the correction of the cause of the [disease]” (Stephenson 1927). Chiropractic treats illnesses by associating the spine with the nervous system and relying on the self-healing attributes of the human body (Bodeker et al. 2005). Chiropractors hold diverse, indeed conflicting, views on the nature of illnesses chiropractic is efficacious in treating, its usefulness ranging from narrow to expansive (Benedetti and Macphail 2018).

Practitioners fall within two groups: the first group heals illnesses only through manipulation of spinal joints, while the second group combines chiropractic methods with other forms of CAMs, predominantly naturopathy, homeopathy and acupuncture, to heal patients; the majority of chiropractors are believed to fall into the latter group (Azari 1999).

Chiropractic and its practitioners are more closely regulated than are other CAMs, with the exception of osteopathy (see Table 5).

Osteopathy

Andrew Taylor Still, a physician from the United States, developed osteopathy in 1874 after he found biomedicine to be ineffective in curing his three children of meningitis (Baer 2009, 26; Duffin 2010, 159). Osteopathy is a form of musculoskeletal therapy that aims to restore movement and relieve pain by massaging bones and muscles, optimizing the body's self-healing capabilities. Therapy is combined with advice on diet and exercise. Some practitioners also use acupuncture to heal patients.⁸ Table 6 shows how osteopathy is regulated in our sample jurisdictions.

Acupuncture

Acupuncture, developed in China over two thousand years ago (see Barnes 2005), involves inserting fine needles at specific points in the body to treat illnesses. Originally considered to be a feature of traditional Chinese medicine (TCM), today acupuncture is practised under the theoretical frameworks of both TCM and biomedicine (Andrews 2014; Vickers and Zollman 1999; Welsh and Boon 2015, 248; Wiesene et al. 2012, 61). TCM acupuncture aims to correct the strength and quality of qi – energy that flows through the body – while biomedical practitioners such as doctors, physiotherapists, nurses and midwives diagnose and treat patients based on physiological and anatomical knowledge (Gale and McHale 2015; Vickers and Zollman 1999). Table 7 summarizes the regulatory regime for acupuncture in the sample jurisdictions.

Traditional Chinese Medicine

Traditional Chinese medicine originated over three

8 See National Academy of Osteopathy, “Frequently Asked Questions,” available online at <http://www.nationalacademyofosteopathy.com/faq.html>; OM Osteopathy, “What Is Osteopathy?” available online at http://www.omosteopathy.co.uk/omo_brochure.pdf; and Ontario School of Osteopathy and Alternative Medicine, “FAQ about Osteopathy,” available online at <http://www.osteopathycollege.com/faq-about-osteopathy.html>.

Table 5: Regulation of Chiropractic, Selected Jurisdictions

| Jurisdiction | Regulatory Approach |
|----------------|--|
| Canada | <ul style="list-style-type: none"> Statutorily regulated through a licensure regime in all provinces, and in Yukon Territory. Subject to self-regulation by colleges (set up under provincial statutes). |
| United States | <ul style="list-style-type: none"> Statutorily regulated through a licensure regime in all states. In some states, the practice is subject to self-regulation; in others, it is a combination of “self-regulation under an interdisciplinary board” (e.g. a medical licensing board (Chapman-Smith 1997, 443)). |
| United Kingdom | Statutorily regulated through a licensure regime. |
| New Zealand | Statutorily regulated through a licensure regime. |
| Australia | Statutorily regulated through a licensure regime. |
| Europe | <ul style="list-style-type: none"> Statutorily regulated in 26 out of 39 countries as of 2012. Regulations vary: in Italy, chiropractic can be practised only by biomedical practitioners who have obtained a qualification in chiropractic, while in Germany, chiropractic is not specifically statutorily regulated and there are few restrictions on who may practise and call themselves a chiropractor. |

Source: Authors' compilation.

thousand years ago (see Unschuld 1985; Yu et al. 2006). Based upon the Chinese philosophies of *yin* and *yang*, and *qi*, TCM treats illnesses by restoring balance and appropriate energy flow in the body (Keji and Hao 2003). TCM practitioners use a variety of methods to prevent and treat illnesses, often combining Chinese herbal medicines with nutritional advice, exercises (such as *tai chi* and *qigong*), massages (such as *tui na*), acupuncture and moxibustion (a form of heat therapy), to name a few (Chan et al. 2015, 68; Yu et al. 2006).⁹ Table 8 shows how TCM is regulated in the various jurisdictions. Several countries also regulate the sale

of Chinese herbal medicines, but in different ways, as Table 9 indicates.

Western Herbal Medicine

Western herbal medicine (WHM) is often viewed as having its roots in Greco-Roman medicine (Francia and Stobart 2014; Tierra 2017).¹⁰ To prevent and treat illnesses, practitioners use plants and their parts – root, stem, flower, bark – in their natural form, unlike biomedicine, which typically uses synthesized forms.¹¹ Currently, two forms of WHM are practised: traditional WHM

9 See also College of Traditional Chinese Medicine Practitioners and Acupuncturists in Ontario, “About TCM,” available online at <https://www.ctcmpao.on.ca/public/about-tcm/>.

10 See also Australian Natural Therapists Association Limited, “Courses,” available online at http://www.australiannaturaltherapistsassociation.com.au/courses/recognised_naturopathy.php.

11 See International Holistic Center of Natural Medicine, “Western Herbal Medicine,” available online at <http://www.ihcnm.com/>; and Therapy Directory, “Western Herbal Medicine,” available online at <http://www.therapy-directory.org.uk>.

Table 6: Regulation of Osteopathy, Selected Jurisdictions

| Jurisdiction | Regulatory Approach |
|-------------------------------|--|
| Canada | <ul style="list-style-type: none"> In Ontario, British Columbia and Alberta only licensed biomedical practitioners registered with the provinces' College of Physicians and Surgeons fulfilling certain educational qualifications can call themselves osteopaths or osteopathic physicians. In these three provinces, non-medical practitioners refer to themselves as manual osteopathic practitioners, and are subject to voluntary, private certification. Other provinces: voluntary, private certification. |
| United States | <ul style="list-style-type: none"> Can be practised by osteopathic physicians and osteopaths. Osteopathic physicians, also referred to as doctors of osteopathy (DO), are biomedical doctors who have also studied osteopathy. Osteopaths are non-biomedical practitioners, and cannot prescribe biomedicines or perform surgery. All states statutorily regulate DOs and osteopaths through licensure regimes. Licensed osteopaths/DOs may choose to be certified by the American Medical Association or osteopathy specialty boards in specialized areas of practice. |
| United Kingdom | <ul style="list-style-type: none"> Statutorily regulated through a licensure regime: only individuals registered in the UK Statutory Register of Osteopaths are permitted to practise and call themselves an osteopath. |
| New Zealand | <ul style="list-style-type: none"> Statutorily regulated through a licensure regime: only individuals registered with the Osteopathic Council of New Zealand are permitted to practise and call themselves an osteopath. |
| Australia | <ul style="list-style-type: none"> Statutorily regulated through a licensure regime: only individuals registered with the Osteopathy Board of Australia are permitted to practise and call themselves an osteopath. |
| Europe | <ul style="list-style-type: none"> Of 39 countries, statutorily regulated in 15 as of 2012. Some countries have taken a strict view on who may practise osteopathy, while others have left the practice statutorily unregulated. For example, in Italy, osteopathy can be practised only by biomedical practitioners who have obtained a qualification in osteopathy; in Austria, osteopathy is neither recognized nor prohibited, and can be practised by individuals with or without medical training. In Germany, osteopathy is not a distinct profession; osteopathic practice is limited to biomedical physicians, physiotherapists and <i>Heilpraktiker</i>, but the training required for the three categories of professionals to be eligible to practise osteopathy differs. |
| Source: Authors' compilation. | |

and phytotherapy. The former relies primarily on traditional knowledge, and emphasizes holistic and individualistic treatment (Baer 2004; Coulter 2004), while phytotherapy relies on contemporary knowledge of physiology and anatomy, and uses

herbs whose efficacy and safety are substantiated by scientific empirical studies (Heinrich et al. 2004).¹²

WHM is often also referred to as “herbal medicine.” Although other CAMs, such as traditional Chinese medicine, also use herbs to treat

12 See also Australia Traditional Medicine Society, “Western Herbal Medicine,” available online at <http://www.atms.com.au/>; and Victoria Community Acupuncture, “Phytotherapy & the Benefits of Plant Medicine,” available online at <http://www.vcaspa.com/>.

Table 7: Regulation of Acupuncture, Selected Jurisdictions

| Jurisdiction | Regulatory Approach |
|----------------|--|
| Canada | <ul style="list-style-type: none"> Medical doctors are permitted to practise in all provinces. Practise by non-medical professionals is regulated through a certification regime in British Columbia, Alberta, Quebec, Ontario and Newfoundland and Labrador, and the title “acupuncturist” is protected. Non-medical professionals may include massage therapists, chiroprodists, chiropractors, occupational therapists and TCM practitioners. Saskatchewan and Yukon Territory have issued guidelines on the practice of acupuncture. |
| United States | <ul style="list-style-type: none"> Most states statutorily regulate either through certification or licensure regimes. |
| United Kingdom | <ul style="list-style-type: none"> Medical and non-medical practitioners may practise. Practise by medical professionals is statutorily regulated – for example, practise by GPs, nurses and physiotherapists is regulated by the General Medical Council, the Nursing and Midwifery Council and the Health and Care Profession Council. Non-medical members who practise acupuncture may choose to become members of private self-regulating associations. Anyone practising acupuncture (whether a member or not) can call themselves an acupuncturist. |
| New Zealand | No statutory regulation; voluntary, private certification. |
| Australia | <ul style="list-style-type: none"> Medical and non-medical professionals may practise. To call oneself an acupuncturist and claim to practise acupuncture, an individual must be registered with the Chinese Medicine Board of Australia (CMBA). The CMBA is established under the governance of the Australian Health Practitioner Regulation Agent (AHPRA), which is responsible for the registration of all health practitioners in Australia. |
| Europe | <ul style="list-style-type: none"> Of 39 countries, statutorily regulated in 26 as of 2012 through a range of regulatory regimes: in some countries via government-approved certification, in others, practise is limited to physicians with specialization in acupuncture. A few countries, such as Italy and France, have chosen to limit practise to biomedical professionals, such as doctors and midwives. In Denmark and Sweden, both medical and non-medical professionals may perform acupuncture. There are no statutory qualification criteria that practitioners must fulfil prior to treating individuals. The only requirement is that patients must not be put at risk. |

Source: Authors’ compilation.

illnesses, WHM practitioners argue that WHM is a distinct herbal medical practice. The commonly cited differences are that principles behind the treatments are vastly different – *yin* and *yang* and

qi in TCM, in contrast to anatomy and physiology in phytotherapy – and that herbal medicines used in TCM are a complex mix of herbs, while WHM typically employs a single herb or only two or

Table 8: Regulation of Traditional Chinese Medicine, Selected Jurisdictions

| Jurisdiction | Regulatory Approach |
|-----------------------|---|
| Canada | <ul style="list-style-type: none"> Regulated only in British Columbia and Ontario. Only registered members of the College of Traditional Chinese Medicine Practitioners and Acupuncturists of British Columbia and the College of Traditional Chinese Medicine Practitioners and Acupuncturists of Ontario, respectively, are allowed to call themselves a TCM practitioner. Only registered members are permitted to prescribe a TCM diagnosis based on TCM philosophy. Other provinces: voluntary, private certification. |
| United States | <ul style="list-style-type: none"> Most states regulate through certification or licensure regimes. |
| United Kingdom | No statutory regulation; voluntary, private certification. |
| New Zealand | No statutory regulation; voluntary, private certification. |
| Australia | <ul style="list-style-type: none"> Regulated through a licensure regime: only “Chinese medicine practitioners” registered with the Chinese Medicine Board of Australia are permitted to practise. |
| Europe | <ul style="list-style-type: none"> Statutorily regulated in 10 of 39 countries as of 2012. In some countries, such as Italy and Austria, the practise of TCM is restricted to medical doctors. Several countries have permitted non-medical practitioners to practise subject to fulfilling conditions such as minimum educational requirements; others have not restricted who may be eligible to practise. |

Note: In Newfoundland and Labrador, although the College of Traditional Chinese Medicine Practitioners and Acupuncturists of Newfoundland and Labrador has been established, acupuncture is regulated, while TCM is not.

Source: Authors' compilation.

Table 9: Regulation of Chinese Herbal Medicines, Canada and the United States

| Jurisdiction | Regulatory Approach |
|----------------------|---|
| Canada | <ul style="list-style-type: none"> Fall under the category of “natural health products” along with vitamins, minerals and probiotics. Natural health products are available without prescription, but can be sold only after being licensed and issued a natural product number from Health Canada. The standard of safety and efficacy proofs needed to qualify for licensing differ from those needed for biomedicines, as continued historical use is accepted as evidence of efficacy. |
| United States | <ul style="list-style-type: none"> Sale of Chinese herbal medicines that qualify as “dietary supplements” are not subjected to mandatory review or testing for purity or potency of active ingredients. |

Source: Authors' compilation.

three.¹³ Table 10 shows how WHM is regulated in the sample jurisdictions. As Table 11 shows, herbal medicinal products are more extensively regulated than WHM in most jurisdictions.

DISORDER IN THE BORDERLANDS

Divergences in Regulatory Practices and Reform Proposals

A striking, even disconcerting, feature of the evolution and regulation of the various CAMs is the lack of anything approaching consistency of approach across jurisdictions and categories of CAMs. Indeed, a range of regulatory options has found favour in one or another Western jurisdiction, with little evidence of a convergence toward a dominant regulatory paradigm.

This discordance in regulatory practice is echoed in scholarly and public policy literature debating the merits of alternative regulatory approaches to CAMs. Some authors oppose regulation of CAM practitioners and products, arguing that typical forms of regulation protect mainstream biomedicine and hinder innovation and competing methods of healing, including traditional CAM practices, some of which are of cultural significance to their communities of origin even where not based upon biomedical epistemology (Cohen 1996, 86; Ijaz et al. 2016, 97, 104; Lindsey and Teles 2017, chap. 5). Other commentators argue against regulation of CAM practitioners and products from opposing premises: that any form of regulation of CAMs is likely to legitimize and promote their use by the public, even though many, if not most, CAM practices and products lack adequate scientific justification or verification (McHale and Gale 2015, 375; Robbins 2010; Robotham 2012).

Among scholars who favour some form of regulation of CAM practitioners, proposals vary widely. Some argue for state-sanctioned forms of self-regulation for individual classes of CAMs, modelled on standard approaches of self-regulation of mainstream professions (Walker and Budd 2002, 10; Wardle 2014; Weir 2005, 179–80). Other scholars argue for an umbrella regulatory body that would regulate all or most forms of CAM practitioners according to a uniform and consistent set of principles (Ries and Fisher 2013, 295–6; Van Hemel 2001, 330). As to what form professional regulation should take, some scholars favour a form of licensure, on the grounds that only licensure regimes are capable of mandating appropriate training regimes, post-entry codes of conduct, and disciplinary and continuing education protocols, which in combination ideally would exclude inadequately trained, fraudulent, incompetent or deviant practitioners or aspiring practitioners from the domain of practice in question (Clark 2004, 392). Other scholars argue – convincingly, in our view – that any attempt to create multiple mutually exclusive licensure regimes across the entire landscape of healthcare provision inevitably would entail arbitrary boundary drawing, rigidities and interprofessional conflicts, as well as impeding innovation and discouraging the closer integration of biomedical and CAM health disciplines (Baron 1983, 346; Gellhorn 1976, 6; Hogan 1983, 126; Olson 1983; Weir 2005, 182–3).

We do not presume in this *Commentary* to offer detailed regulatory protocols for each individual category of CAM, or CAMs as a broader encompassing category. Rather, we propose general guiding regulatory principles for CAM products and practitioners.

13 See Healing Foundations, “Chinese Herbs and Western Herbs: Is There a Difference?” available online at <https://patch.com/>; and LAN Acupuncture and Herbal Medicine, “Herbal Medicine FAQ,” available online at <http://www.lanacupuncture.com/>.

Table 10: Regulation of Western Herbal Medicine, Selected Jurisdictions

| Jurisdiction | Regulatory Approach |
|-------------------------------|--|
| Canada | No statutory regulation; voluntary, private certification. |
| United States | No statutory regulation; voluntary, private certification. |
| United Kingdom | No statutory regulation; voluntary, private certification. |
| New Zealand | No statutory regulation; voluntary, private certification. |
| Australia | No statutory regulation; voluntary, private certification. |
| Europe | Of 39 countries, 10 statutorily regulate as of 2012. |
| Source: Authors' compilation. | |

Table 11: Regulation of Herbal Medicinal Products, Selected Jurisdictions

| Jurisdiction | Regulatory Approach |
|-------------------------------|--|
| Canada | Fall under the category of “natural health products” and are subject to a similar approval process. |
| United States | Fall under the category of “dietary supplements” subject to lower scrutiny than over-the-counter medicines. |
| United Kingdom | Sales and products regulated at the EU level since 2011 (see below); this might be subject to change on account of Brexit. |
| Australia | <ul style="list-style-type: none"> Regulates as therapeutic substances through a two-tiered system categorized on the basis of risk, requiring products to be either registered or listed prior to sale. Higher-risk medicines, including WHM, can be sold only after being registered with the Australian Register of Therapeutic Goods (ARTG), pursuant to which each product is individually evaluated for quality, safety and efficacy. Traditional use as proof of safety or efficacy is accepted to a very limited extent. Lower-risk medicines comprising pre-approved, low-risk ingredients and making limited claims are listed on the ARTG, and are not subject to the same individualized scrutiny as higher-risk medicines. |
| Europe | <ul style="list-style-type: none"> Prior to sale, all herbal medicinal products must obtain market authorization or be registered under the Traditional Herbal Registration process. Efficacy and safety must be substantiated, although, unlike biomedicines, they may be validated through traditional historical use since it was recognized that many herbal products would be unable to fulfil the evidentiary requirements imposed on biomedicine. |
| Source: Authors' compilation. | |

Risk Calibration

First, recognizing that the two principal motivating rationales for regulation of healthcare provision generally – severe information asymmetries between healthcare practitioners and patients and, to a lesser extent, negative externalities associated with patients’ healthcare decisions or caregivers – it seems a relatively uncontroversial starting premise that regulatory responses should be calibrated to the degree of risk entailed, principally for patients, but in some cases for third parties. Risk is commonly thought of as a product of the probability of a negative contingency occurring and the severity of the consequences of that contingency in the event that it does occur – often characterized as the “expected cost” of a decision to assume the risk in question. This approach to health-related risks would seem to explain much, albeit not all, of the detailed regulation of biomedicine (both procedures and products) commonly observed in almost all Western countries.

One implication we draw from the biomedical regulatory paradigm now deeply entrenched and widely observed in most Western jurisdictions is that it is difficult, if not impossible, for the state to sustain a purely *laissez-faire* approach to the provision of CAM products or services. The consequence of not regulating CAMs might be that individuals erroneously believe that a public authority has determined that these products or services are at worst harmless and at best helpful in alleviating the medical conditions that proponents often claim they are able to address. In many cases, however, the lack of regulation of CAMs does not reflect a conscious decision by government: certain CAM products or services, such as Western herbal medicines or naturopathy, might be harmful if taken in concentrated form or in excessive doses or for protracted periods of time. Perhaps of greatest concern, claims of efficacy in dealing with serious health conditions often might be unwarranted, and

might deflect patients or caregivers from pursuing more efficacious biomedical treatments (Brody 2018).

Second, on the scale of risk, from trivial to severe, some forms of CAM products and services clearly fall toward the trivial end of the spectrum. For example, forms of CAM products or services that address dietary or lifestyle concerns or common forms of coughs and colds and aches and pains of the kind that many individuals treat with home remedies or over-the-counter medications would seem to warrant minimal regulation beyond mandatory warnings of potentially serious side effects if, as in the case of herbal medicines, taken in excess. In such cases, the absence of appropriate warnings might trigger penal sanctions and potential tortious liability, and would remain subject to general prohibitions against fraudulent, false or misleading advertising claims.

Third, other forms of risk fall toward the more serious end of the scale, where proponents claim that certain CAM products or services are able to address serious life-threatening forms of health conditions, including infectious diseases, as alternatives to conventional forms of biomedicine whose efficacy has been scientifically validated. Obviously, a lesser degree of risk is entailed where CAM practices or products are promoted as complements to biomedical treatments, rather than as substitutes, although negative interactions between two types of treatment for the same condition might increase risk factors in some contexts.

Fourth, we believe that some general policy orientations emerge from this risk calibration approach to the regulation of CAM products or services. For forms of CAMs that fall toward the trivial end of the risk spectrum, light-handed *ex ante* regulation seems appropriate, providing a relatively large scope for patients’ autonomy in the choice of medical treatments. For forms of CAMs that fall toward the higher end of the risk spectrum, it seems difficult to justify a completely *laissez-faire*

position on the part of the state. In effect, where a CAM treatment is not directly harmful and is not marketed to displace biomedical treatments for serious health conditions, we recommend a “negative regulation” approach that exempts the treatment from regulation beyond general misleading advertising laws.

Certification but not Licensure

In general, with respect to the *ex ante* regulation of CAM practitioners, we favour state-sanctioned forms of delegated self-regulation of certification regimes by practitioners themselves, where designated titles would be reserved for accredited members of the state-recognized governing bodies, but not mutually exclusive areas of practice, as under licensure regimes. Formal certification regimes are likely to create a strong incentive for certification bodies and their members to promote their brand and reputational status among the public and medical practitioners generally. This would solidify internal norms by proscribing outlier practices without all the negative features of an exclusive licensure regime, as noted above. While not entitled to the protection of an exclusive licensure regime, members in good standing of an official certification regime might be granted immunity from prosecution for the unauthorized practise of medicine as a further inducement to seek and maintain accreditation. Members disciplined for malpractice could be decertified, but not prohibited from continuing as uncertified practitioners. Public records of suspensions and decertification of practitioners could partially address information asymmetry concerns on this score.

Supervised Self-regulation

To minimize the risk of overreach in the healthcare claims of members of CAM professional

certification bodies and their members, there might be merit in the creation by government of an overarching advisory body – a CAM advisory council – to which the various self-regulatory regimes would be required to submit their regulations governing education and training, codes of conduct, and disciplinary procedures. The council would review these and advise government whether to adopt or reject the proposed regulations (but not to initiate regulations). In exercising this review function, such an advisory body – ideally comprised of representatives of the various CAM disciplines, patient or consumer groups and the medical and scientific research communities – would identify practices that are high risk and that members of these governing bodies would be prohibited from engaging in or promoting, as well as practices that would facilitate the greater integration of CAMs and biomedicine. Prohibition of defined practices might also be extended to non-members.

In exercising this oversight function – in particular the determination of prohibited practices – such an advisory body might adopt a standard that, in the presence of scientific controversy or disagreement, might reflect minority, as opposed to mainstream, scientific opinion, provided the minority opinion comes from qualified and respected sources, recognizing that government would want to act from perspectives of prudence and caution where risks of irreversible damage to human health are concerned.

For an appropriate standard for regulated CAM treatments as substitutes for biomedical treatments for serious health conditions, we suggest adopting the “minimum standard of proven scientific efficacy” threshold. In the trade law context, this standard was employed by the World Trade Organization’s Appellate Body to adjudicate whether regulations restricting imports of beef hormones were an unjustified discriminatory trade measure or a legitimate protective measure.¹⁴ The Appellate Body

14 See the Appellate Body decision in the *Beef Hormones* case (1998), available online at https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds26_e.htm.

held that a country imposing such restrictions for a purported precautionary purpose was not required to establish full scientific proof, but must show some minimum scientific basis for supporting a precautionary measure. We suggest that this is also an appropriate standard for determining whether CAM treatments that displace biomedical therapies for serious health conditions nonetheless should be permitted. This “minimum scientific basis” threshold would delineate a zone for individuals to choose their own treatment from a zone where a treatment lacks a basis for any reasonable claim of therapeutic effectiveness and the risk of misrepresentation is unacceptable.

We consider this approach equally appropriate for both CAM products and services. In the context of the regulation of CAM practitioners and products, an application would require that at least the minimum scientific justification be met for cases where CAM services or products are promoted as an alternative to biomedicine in treating conditions entailing potentially irreversible damage to human health.

CAMs as Complements to or Substitutes for Biomedicine

In cases where some forms of CAMs are promoted as complements to biomedical treatments of the same condition, perhaps a somewhat less demanding standard might be appropriate by way of promoting the greater integration of biomedicine and CAMs – for example, in the absence of scientific evidence that CAM products or services cause direct harm or raise the risk of serious side effects. Integration is a valuable tool for reducing information asymmetries and potentially decreasing negative externalities, as it might foster better referral practices between biomedical and CAM practitioners and better communication between practitioners and their patients.

Although CAM products should be subject to scrutiny by food-and-drug-safety agencies, given that they are often purchased without the intermediation or advice of a CAM practitioner,

there are limitations. For example, herbs prescribed in their natural form are likely to be freely available in markets, and hence would not fall under such agencies’ scrutiny or be subjected to prescribed labelling standards; some CAM prescriptions are individualized, as in TCM; and agencies’ limited resources of funds or time would preclude their scrutinizing each CAM product. Bearing in mind these limitations, regulation of commercial preparations of CAM products by food-and-drug-safety agencies should apply the following principles:

- for minor illnesses for which over-the-counter biomedicines are commonly purchased for self-medication, a “no harm” principle should apply to commercial preparations of CAMs;
- where CAM products are promoted as a complement to biomedicine, even for serious illnesses, a “no harm” principle should also apply to commercial preparations of CAMs; and
- where CAM products are promoted as an alternative to biomedicine in the treatment of serious health conditions, the minimum standard of proven scientific efficacy should apply.

***Ex post* Regulation of CAM Products and Services**

The *ex post* regulation of CAM products and services by courts, regardless of whether falling toward the trivial or the higher end of the risk spectrum, remains critical so as to ensure that persons responsible (including non-certified practitioners and other third parties) are held liable for fraudulent, false or misleading advertisements or claims, tortious liability for negligence or criminal liability for gross negligence. When determining such violations, the criterion of a minimum standard of proven scientific efficacy should be applied to cases where claims or advertisements promote a CAM product or service as an alternative to biomedicine in the treatment of life-threatening health conditions.

CONCLUSION

This paper has provided a framework for governments to structure the regulation of complementary and alternative medicines and develop appropriate institutions, such as a CAM advisory council, to provide independent advice to governments on appropriate standards for CAMs, especially when promoted as alternatives to biomedical treatments for serious health conditions.

Advice on medical treatments involves significant information asymmetries and potentially engages mortal risks for individuals. A principled and restrained approach to regulating CAM would focus on calibrating regulatory responses to the

seriousness of the risks involved and reflect an appropriate balance between personal autonomy/patient choice and the public interest in addressing misrepresentations.

We do not claim that this articulation of general principles would resolve regulatory debates on the ground with respect to the various classes of CAMs. However, although many question the legitimizing CAMs, the growth of the use of CAM treatments indicates that consumer demand for them is here to stay. What is needed are clear regulatory objectives, principles and independent, expert institutions in order to shape the appropriate regulation of complementary and alternative medicines.

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