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THE RELATION BETWEEN THE ADVANCEMENT OF CAM KNOWLEDGE AND THE REGULATION OF BIOMEDICAL RESEARCH

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em·pir·ic
n.
1 a person who relies on empirical methods
2 (Medicine) a medical quack; charlatan
adj.
empirical.

(Collins English Dictionary, *HarperCollins, 2003)*

I Introduction

Knowledge, law, and the state are intimately connected. The advancement of knowledge through research and development is never completely lawless (Stokes 2012, Golan 2004); instead, it often emerges with the support of an array of regulatory apparatuses, audit practices, and public subsidies. In turn, policies, and legislative and judicial decisions are increasingly developed under the influence of experts in various bodies of knowledge (Fischer 1990, Irwin 2008).

However, the state is not neutral vis-à-vis all 'forms of knowledge' as taken in their broadest sense (de Camargo 2002, Casey and Picherack 2001). In fact, it simply could not be. State recognition and support rather tend to be geared towards formal knowledge, understood as a 'cognitive content acquired from formal education, professional practice or technoscientific literature' (de Camargo 2002: 828). The type of knowledge that the state is interested and invested in is actually even more restricted than that: more often than not it refers to bodies of knowledge that live up to what are commonly recognized as 'scientific standards'. This is particularly patent in the context of health care, where policymakers increasingly use evidence-based medicine (EBM) as a basis for decision-making. In order to receive the state imprimatur, diagnostic methods and therapies ought to prove efficient according to conventional medicine's scientific standards, especially the randomized clinical trial (RCT) method. Legal scholar Ireh

Iyioha thus aptly speaks of a 'nexus between statutory legitimacy and scientific validation of health systems' (2011: 1; see also Polich *et al.* 2010).

It might not come as a surprise, then, that in the eyes of the public, scientists, like politicians, bureaucrats, and businessmen, are under increased scrutiny. The public now demands integrity, accountability, and transparency from all spheres of public life. Hence the science–law–state nexus is itself up for grabs. This is part of the context in which complementary and alternative medicine (CAM) researchers currently work.

In this chapter, I am interested in CAM as a mode of knowledge production, and in how CAM and the 'state law's espousal of science' (Santos 2002, Iyohia 2011) negotiate each other. The chapter aims to explain the way the state–knowledge–law nexus operates in the context of CAM, to identify tensions and potential in that operation, and finally to point towards an alternative model/pathway that might allow the alternative knowledge base (or disciplinary ecology) of CAM to have a greater impact on its own patterns of governance. I hope the chapter will invite a reflection on how CAM mimics and resists mainstream biomedicine in the context of research, and about the way legitimation can iron out distinctiveness.

I come to CAM research's engagement to regulation from the perspectives of socio-legal studies. To be brief, socio-legal scholarship is an interdisciplinary field that has long assumed an outsider's perspective on law (Riles 1994) as well as an interest in 'law in action' as much as in 'law in the books'. Socio-legal scholars have examined the way law (mainly positive law, see Constable 2008) is experienced in its 'trenches', that is, from below, or from an outlaw's perspectives. More recently, socio-legal scholars have also began to study law's 'ivory towers' – that is, they have approached law by self-consciously describing it from the top down by paying attention to the actors that craft law's legitimacy and power. Some socio-legal scholars have employed their empirical, theoretical, doctrinal, and critical tools to examine the relationship between law and other privileged professions, such as medicine (Feldman 2000, Jacob 2012, Cloatre 2013). The field of socio-legal studies also increasingly converses with science and technology studies (Valverde 2003, Faulkner *et al.* 2012, Cloatre and Pickersgill 2014).

This chapter is based on a literature review on the topic and does not provide empirical claims, although it is inspired by fieldwork begun in 2010 in the milieu of research governance (Jacob 2014).[2] With respect to the concept of *knowledge* of biomedical and CAM research, I try to adopt a middle-ground approach: I aim to surpass the rehearsed distinctions found in legislation and policies about scientific vs. non-scientific knowledge, and to encompass less formal and official modes of knowing, but I do not aim to discuss high-level epistemological debates as to what counts or should count as 'knowledge'. I hope readers will forgive the loose ways with which I engage with that division. In fact, if you are reading this handbook you are probably accustomed to this problem and struggle with it, as it seems endemic to any conversation about CAM. So, what indeed does constitute CAM knowledge?

II CAM knowledge and CAM rhetoric

Historian Roberta Bivins suggests that to have medical systems, theories, and practices that can 'be regarded as "alternative" one must have a recognized, definable, and at least relatively stable orthodoxy to which they oppose themselves' (Bivins 2010: 171). In other words, the world of CAM itself would be founded on a binary, as discussed in the introduction to this handbook. This is illustrated at several junctures in this chapter. In practice, Bivins' observation means that 'boundary-work' constitutes, unavoidably, an important part of the self-fashioning of CAM knowledge. Initially, 'boundary-work' (Gieryn 1983) referred to the discursive practices of scientists as they stress their difference and superiority over less 'authoritative' forms of non-scientific

knowledge. Since then, it has been interpreted more broadly, as a strategy taken up by a group, an institution, or profession (Gieryn 1983, Thomson 2013), to assert its epistemic authority, or perhaps even more generally its distinction, by working out boundaries around its expertise. Gieryn calls the resulting boundaries 'lines in the sand', hence highlighting how strategic and volatile they are. CAM proponents have shown up their distinct contribution in such ways.

For instance, the entire venture of CAM could not exist without a mode of opposition. Seventeenth-century 'empiricism', which was an alternative to the mainstream medicine of the time, explicitly showcased 'the promise of freedom, the bolster against tyranny, and the endorsement of individual ambition', and was associated with subversiveness against dogmas (Benedict 2001: 26–7). One interpretation of the genealogy of CAM knowledge (in the Western world) is that it emerged in the nineteenth century out of the holistic movement from within medicine, based on alternate models in medicine, including the biopsychosocial model. The tone of the proponents was resolutely oppositional. Holist thinkers also rapidly distanced themselves not only from orthodox, reductionist medicine, but from notions of 'medical progress' and modern technological civilization. They also criticized what they saw as the dehumanization of society (Weisz 1998: 75). Rosenberg notes that, throughout the twentieth century, well-known 'jeremiads against fragmentation, alienation, against reductionism of market-oriented social relations' (1998: 337) have at once paralleled and supported different forms of medical holism, such as the one put forward by some CAM approaches.

In addition, scholars of CAM have marshalled distinctions and binaries coming from within the field of CAM itself. Historian Roy Porter (1989) has provided the very useful distinction between the rhetoric and the practice of CAM. Self-fashioning is critical in the field. The very term 'alternative' carries positive baggage and can almost immunise CAM to critique in some ways. Who can be against a medicine that does things differently, is more informal, humane, context based?[3] The term 'natural', which is often associated with CAM, carries its own normative load (Anderson 2010). CAM researchers have described themselves as being 'on the edge' (Polich *et al.* 2010: 112). Note that in the context of this chapter, we should be wary not to associate CAM with necessarily progressive views and cutting-edge critiques of research and regulation, as CAM is also likely to produce romantic, conservative approaches to research which are suspicious of the mainstream for regressive, back-to-nature kinds of reasons.

Those who study CAM ought to pay attention to its alignment with the powerful rhetoric of alternativeness, and analyse them against CAM practices that can be rather conformist, mainstream, and mercantile (Porter 1989). CAM researchers have been agile at negotiating the boundaries between CAM and biomedicine, and position their CAM research on the spectrum of CAM therapies (Polich *et al.* 2010, Wolffram 2010). To do this, CAM researchers use 'scientific terminology', de-emphasize certain aspects of their work, highlight their 'conventionality' (Polich *et al.* 2010: 113), and compare themselves to the less mainstream, that is, distance themselves from alternative medicine and see themselves as closer to norms of biomedical research. Note that the boundary-work is also mobilized in opposite ways, in order to emphasize the dividends of the 'difference' that CAM offers (Micollier 2011: 59). These positionings, as we will see, extend to the engagement of CAM researchers with research regulation, and hence they are at the centre of this chapter.

The science-culture is another binary that is critical to the self-making rhetoric of CAM research. CAM researchers confront the assumption, particularly tenacious, that science is culture-free. Interestingly science and technology studies scholars have used the metaphor of magic to describe how science has managed to remain cut off from culture: 'laboratory science … still moves around the globe like a fetish, with its social relations conveniently erased. It seems to arrive with capitalism, "like a ship," then magically arrive elsewhere, just as powerful,

packaged, and intact' (Anderson and Adams 2008: 182). This particular account might be overstating the point, but it rightfully directs to the problems faced by knowledge that stands outside the 'intactness' of science. CAM knowledge, in contrast to science, is perceived as belonging to the sticky realm of culture, of religion and magic (Langford 1999). As mentioned above, CAM researchers often use boundary-work to distance themselves from culture and align themselves with science.

However, again, we ought to remain careful not to caricature the difference between biomedicine and CAM. Science is increasingly aware of its cultural specificity and attuned to postmodernism (see Saks 1998). As an illustration, the Cochrane Collaboration defines CAM as a domain of healing resources 'other than those intrinsic to the politically dominant health system of a particular society or culture in a given historical period' (Zollman and Vickers 1999: 693). 'Boundaries', as it reads in this *British Medical Journal* article, 'between the CAM domain and that of the dominant system are not always sharp or fixed' (Zollman and Vickers 1999: 693).

In the next sections, I will discuss the connection, and possible mismatch, between CAM research and the regulatory benchmarks of science – in particular, the randomized controlled trial. This dissonance is illustrated, but also modulated, when looking at state-sanctioned hierarchies of evidence. Next, I will contextualize the discussion within the larger issue of the state's commitment towards science. I will conclude that. contrary to common wisdom, the norms and practices of CAM research make it more similar in form and technique to biomedical research than we might think. The puzzle for CAM, then, may well lie in how to translate the alternativeness of its knowledge into genuinely alternative research practices. CAM knowledge-makers might ask themselves whether they can and should contribute to further defining what it means to produce trustworthy knowledge, or enacting alternative research regulation.

III The regulation of non-CAM research and the scienticization of CAM

Let me turn to an overview of how non-CAM and CAM research is regulated. Mike Saks points out how the increase in scandals and misconduct in orthodox medicine (and arguably, medical research) has benefited CAM by keeping the spotlight on the deficiencies of the ethics and methods of orthodox medicine (Saks 2003; and see Porter 1989).[4] However, in the current climate of rising scrutiny from the public towards science, and of growing demands for accountability and transparency in all public spheres, there are higher expectations about regulation and scrutiny in CAM research as well (Mills 2001).

Let us note at the outset that various commentators have highlighted that contemporary Western biomedicine is increasingly standardized (Timmermans and Berg 2003). The standards in question vary greatly; they can be mandated by state law, but can also be the product of private governance (Faulkner *et al.* 2012). The diversity in standards means that highly standardized medicine is not necessarily a more standard or universal medicine (Timmermans and Epstein 2010). The concept of 'regulatory objectivity' was crafted to refer to this currently dominant model of medicine (Cambrosio *et al.* 2006, Lewis and Atkinson 2011). 'Regulatory objectivity' is a new form of objectivity in biomedicine that generates conventions and norms through concerted programmes of action based on the use of a variety of systems for the collective production of evidence (Cambrosio *et al.* 2009: 651). In line with the insights of science and technology studies, the theorists of 'regulatory objectivity' alert us to ensuing changes to biomedicine itself, not only to its so-called external regulatory environment. In other words, the regulatory frameworks on safety, human subjects, and so on (to which I turn to next) that may seem external to and imposed on biomedicine are in fact more and more *built-in* biomedicine. So-called external regulation from the field of law and ethics gets enmeshed with layers of intrinsic categorizations,

classifications, and measurement regimes (Lezaun 2012), and thus co-produce biomedical knowledge itself (Jasanoff 2008). Today, research is governed *ex ante* through state, research councils, and sponsor guidelines, but also *ex post*, through state, non-state, and self-regulatory responses to scientific misconduct, as outlined below (EMRC 2011, ESF 2010).

1 Ex ante

The *Declaration of Helsinki*, drawn in 1964 but revised several times since 2008, is the first international instrument setting out principles governing research with human participants, whether mainstream biomedical or CAM research. The principles of the Declaration derive from the Nuremberg Code, drafted by judges in the Nuremberg Trial of Nazi war criminals.

Since then, the regulation of medical research, at the international, regional, and national level, has become a 'growth industry' whose voluminous documentation ironically comes in the way of good research practice (Mason and Laurie 2013: 648; see also Jacob and Riles 2007). The internationalization of research has complicated matters further (Anderson and Steneck 2011) by expanding even more the number and levels of regulation. It is beyond the scope of this chapter to offer a comprehensive précis of all the regulatory requirements that apply to modern research.

In Europe, the Additional Protocol to the Convention of Human Rights and Biomedicine Concerning Biomedical Research (2005) sets principles governing research with human participants. The Forum for National Ethics Council attempts to coordinate ethical reflection and to raise and maintain regulatory standards in medical research. The European Directive of 2001 relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use has been implemented by member states. It has been criticized by professional bodies for causing a drop in clinical trials in Europe (Mason and Laurie 2013: 650, and see further below). In July 2012, the European Commission's proposal for a new European Clinical Trials Regulation replacing the Directive has been adopted. This new Regulation is expected to come into effect in 2016.

The UK regulatory framework of clinical research in the UK is not a coherent, across-the-board set of regulations (Dixon-Woods 2010). The main concerns of the UK legal framework and 'research governance culture' (Mason and Laurie 2013: 656) involve responsibility and accountability, as well as consent of participants. Since 1968, following the recommendation of the Medical Research Council, the regulation of medical research consisted of ethics committees (Boden *et al.* 2009, citing Committee of Privy Council for Medical Research 1964). The constitution of these local research ethics committees was sporadic and uneven until the first piece of formal guidance from the Department of Health in 1991 (Brazier and Cave 2011). The first UK piece of legislation consisted of the *Medicines for Human Use (Clinical Trials) Regulations 2004* (amended since) implementing the European Directive. The Department of Health published its Research Governance Framework for Health and Social Care in 2001, with an update in 2005. The Framework establishes the principle of good research governance and clarifies the arrangements for research ethics committees, in line with the legacy of the *Declaration of Helsinki*. An annex published in 2008 provides detailed guidance for areas of research that activate the application of the Mental Capacity Act 2005 or the Human Tissue Act 2004.

Another body of 'legislation, guidance and policy' (MHRA website 2012) is applied by the Inspection, Enforcement and Standards Division of the Medicine and Healthcare Products Regulatory Agency. The MHRA provides oversight over research in the form of trials on medicinal products, including herbal and homeopathic medicines. This set of regulation is thus relevant for CAM research and responds to three main stated policy concerns: first, the protection of

subjects who participate in this research; second, the public interest in the safety of research; and third, the promotion of the research industry. The first two concerns are translated in licensing authorities that oversee research (Hervey and McHale 2004). However, the MHRA does not have oversight over research ethics committees. The third policy concern about the importance of promoting research industry is translated in regulatory requirements of speediness in the licensing and approval processes. The Good Clinical Research Practice Inspectorate is responsible for inspections of research practices (MHRA website 2012).

Recently, criticisms over the over-regulation of research have been voiced and, in 2010, the UK government mandated the Academy of Medical Sciences (AMS) to review the regulation of research with a view of radically simplifying the oversight process. Approximately at the same time though, the National Institute for Health Research published a new standards framework for local NHS research management. The stated objectives related to: 'Bureaucracy – cut red tape and gold-plating of regulation; Accountability – enable the public to hold public bodies to account; Efficiency – cut the costs of administration; and Autonomy – enable front line staff to use their professional judgment'.

In December 2011, the NHS launched a new organization with special authority, the Health Research Authority (HRA), whose purpose is to protect and promote the interests of patients and the public in health research. The HRA intends to work closely with the MHRA to 'create a unified approval process and to promote proportionate standards for compliance and inspection within a consistent national system of research governance' (HRA website 2012) The work of the National Research Ethics Service and of the National Information Governance Board's Ethics and Confidentiality Committee has now transferred to the new HRA.

Another body of rules that concerns both CAM and non-CAM research constitutes legislation regarding the transparency of public bodies (including publicly funded activities) and the handling of personal data. The remit of these legislations (Freedom of Information Act 2000, the Environmental Information Regulations[5] and the Data Protection Act 1998) far extends the domain of scientific research, and their importance was highlighted recently (House of Commons Science and Technology Committee 2011, Russell 2010). Research using personal data (for instance, patient data or samples obtained previously for another purposes) also needs to comply with the laws concerning privacy and confidentiality, as well as with relevant sections of the Human Tissue Act 2004 and its Codes of Practice, and related cases (Lowrance 2012, Mason and Laurie 2013). These legislative instruments all have the consent of the research participant as their 'primary policy device' (Mason and Laurie 2013: 679), while regulators such as the Health Research Authority's Confidentiality Advisory Group in the UK work to strike a balance between consent and the public interest value of research.

The Medicines Act 1968 sets its own requirements as to the quality, safety, and efficacy of medicines before they can be manufactured and put on the market. These regulatory requirements are significant to the ways researchers and their sponsors ought to conduct research on medicinal products. Herbal remedies and homeopathic products can be treated as ordinary medicinal products, but they also have access to a different scheme, the Traditional Herbal Medicine Registration Scheme (THMRS), which only requires proof of quality and safety, but not efficacy. Instead of efficacy (itself a contested term, which I will discuss below), other indicators are used, such as proof of traditional use for various lengths of time (Jackson 2012: 8–18). Such distinct product recognition thresholds signal different, somewhat 'weaker' (Jackson 2012: 12) legal expectations for researchers, sponsors, and manufacturers of complementary and alternative medicines than for biomedical researchers working on conventional medicines.

The industry and other prominent research funders (the Medical Research Council and the Wellcome Trust in the UK, and the National Institutes of Health in the US) have enacted their

own guidelines for the good conduct of research. In addition, the work of the researchers who are registered medics is governed by the General Medical Council (GMC), via its Guidance *Good Practice in Research* (2010) and *Consent to Research* (2010). Irrespective of the disciplines used in their research, researchers who are also registered professionals are bound by their regulatory bodies. Thus, in an analogous manner to medical researchers being regulated by the GMC, CAM researchers who are, say, licensed nurses, chiropractors, or osteopaths have their professional work regulated by their respective professional self-regulatory bodies (see McHale, this volume, Saks, this volume). In addition, complementary health care practitioners are represented as well as regulated by various groups, including the national voluntary regulator Complementary and Natural Healthcare Council, and others like the British Acupuncture Council or the Society of Homeopaths.

Last but not least is the requirement for clinical trials registration as a measure to maintain the integrity and transparency of research (Horton and Smith 1999, Abbasi 2004). In 2004, a consortium of medical journals, the International Committee of Medical Journal Editors (ICMJE), announced that all trials must register in a public trials registry as soon as it starts patient enrolment, in order to be considered for publication in those journals. It is increasingly recognized that underreporting of research can also be a form of research misconduct (Chalmers 1990). There are public trials registries, such as www.clinicaltrials.gov, which is sponsored by the US National Library of Medicine. In the UK, policy for mandatory registration and reporting of all clinical trials has been implemented via the National Institute for Health Research Clinical Research Network (NIHR CRN) Portfolio, a database of high-quality clinical research studies that are eligible for support from the NIHR Clinical Research Network in England in the UK. These have entry criteria that are often not met by many clinical trials conducted worldwide. There are also private trials registries, such as the International Standard Randomised Controlled Trial Number (ISRCTN) registry, hosted by the commercial company Current Controlled Trials (www.controlled-trials.com). These are freely available to the public.

2 Ex post

The UK does not have state regulations overseeing publication, authenticity, and conflicts of interests in research practice. However, different advisory bodies have attempted to define research integrity (Jacob 2013) and to apply definitions to real-life cases. For instance, an international charity which started as a local group in London, the Committee on Publication Ethics (COPE), is providing advice to editors about good practice and research integrity in publishing. Many national or regional agencies, such as the UK Research Integrity Office (UKRIO), act as advisory bodies for researchers and the researchers' institutions, whereas their US, Danish, and Norwegian counterparts[6] have regulatory as well as advisory powers (ENRIO 2014). Research funders also publish guidance about research integrity. Various possible regulatory and non-regulatory responses to occurrences of research misconduct are increasingly debated in the UK,[7] as well as internationally.

The three-prong definition of research misconduct was initially comprised of fabrication, falsification, and plagiarism (LaFollette 1992), but it has since expanded to include: ghostwriting, gift authorship, non-disclosure of conflict of interests, and data editing (Edmond 2008). It has been argued that biotechnologies themselves have prompted novel regulatory and ethical problems (Oliver and Montgomery 2009). For instance, technological breakthroughs generate new ethical questions about genetic engineering, cloning, reproductive rights, and informed consent; industry–university joint ventures pose problems of conflict of interests and disclosure of financial agreements; advances in electronic publication prompt questions about proprietary knowledge and

authorship claims. According to this view, the traditional and 'natural' aspects of CAM would make it less vulnerable to certain newer forms of research misconduct. But note that research misconduct is not in itself a new issue: for instance, the falsification of data is an old problem which can now be expressed in new forms – for example, via image or gels manipulation. In this sense, there is no reason to think that CAM research is immune to basic forms of research misconduct.

In the US context, it has been argued that there is a lack of regulatory oversight of CAM therapies (e.g. chiropractic, acupuncture, traditional oriental medicine, and massage therapy) with respect to the protection of human subjects and of animal populations (Cohen and Schachter 2004). From a scoping overview of the field thus far, it is notable from the outset that CAM researchers have in general created little infrastructure for implementing research integrity and dealing with research misconduct.

In the field of publication ethics, a recent study on journals retractions published in Medline (Wager and Williams 2011) found no retraction coming from CAM journals during 1998–2008 (although it is important to note that not all CAM journals are published on Medline). Between 1997 and 2011, amongst the hundreds of reported cases discussed by the Committee on Publication Ethics (COPE),[8] only one relates to CAM: a case of homeopathy research on AIDS.

Despite the Complementary and Natural Healthcare Council's own statement that decisions made by the investigations committee on conduct and competence will be made available on its website, as of December 2012, no conduct and competence cases had been reported (let alone research conduct cases) on the online database.[9] As US research integrity experts Rennie and Gunsalus (2008: 30) suggest, in the context of research misconduct, an absence of reported cases is more likely to signal a lack of oversight than the absence of misconduct. There is, however, some evidence of infrastructure – for instance, at the National Council for Osteopathic Research, which has published a Research Governance Framework in 2007. The Health Professions Council (which is not a specifically CAM regulator, but regulates, amongst others, art and music therapists) has an easily accessible database of all fitness-to-practice cases, including those related to research activities.

The engagement of CAM research with regulation that we have reviewed so far indicates a one-way, top-down regulator–regulatee relationship, one in which a body of knowledge and knowledge-makers is under regulatory oversight. What kinds of regulatory conversations are taking place between CAM researchers and state and non-state regulators of research?

IV Regulatory engagements

The chapter now turns to exploring how CAM research fares in a highly standardized world, and in the face of biomedicine tailored by 'regulatory objectivity' as referred to earlier. Critical questions to be addressed include: Does the claimed 'alternativeness' of the knowledge base of CAM demand alternative definitions of research conduct and of research governance? In CAM and non-CAM contexts, how do people innovate by crafting alternative and complementary regulatory frameworks? Is the field of CAM not an ideal place to *begin* to rethink the way trustworthy knowledge is produced? Can CAM contribute to thinking about the ways in which research should get regulated by state and non-state actors? Indeed, the idea of an alternative way to do medicine that could positively inspire an alternative way to regulate is not new. This idea developed more than a decade ago, when pioneering legal scholars of CAM, Julie Stone and Joan Matthews, pointed out the need for a 'holistic regulation' (1996: 291) and 'spectrum approach to regulation' (215) as a way to govern complementary medicine. Despite all this, in the context of CAM, the idea of an alternative mode of caring and doing research has not yet triggered a profound rethinking of the idea of research governance and research conduct. Interestingly, the term

'holistic research governance' was used recently in a leading medical law textbook (Mason and Laurie 2013: 679) in reference to new approaches to regulating research that emphasize a broader engagement with ethical, legal, and social implications (ELSI) of biomedicine and to a *reflexive* governance approach that sees research as a partnership between researchers and participants.[10]

The CAM literature is divided as to whether CAM research should follow the same standards as Western biomedical research: some highlight the 'mismatch' between CAM knowledge and the randomized control trial, as mentioned above, and some, to the contrary, go to great lengths to explain the need for robust RCT to provide a research base for CAM knowledge. The 2008 Report of the Department of Health Steering Group on the Statutory Regulation of Practitioners of Acupuncture, Herbal Medicine, Traditional Chinese Medicine and Other Traditional Medicine Systems Practised in the UK (the 'DH Steering Group') illustrates the ambivalence of CAM proponents towards the 'regulatory' force (Cambrosio *et al.* 2006, Micollier 2011) of the RCT. In its discussion of the need for a 'robust evidence base' for these practices, the Steering Group interestingly refers specifically to the European Directive on Traditional Herbal Medicinal Products, which notes that: 'The long tradition of the medicinal product makes it possible to reduce the need for clinical trials insofar as the efficacy of the medicinal product is plausible on the basis of long-standing use and experience.'[11] Yet, when the 'hard' evidence of randomized clinical trials is available and shows the internal and external validity of a technique (for example, for Chinese herbal medicine and acupuncture) (DH Steering Group 2008: 26), the Steering Group seems to uncritically embrace this RCT evidence, and finds it 'essential' in order 'to establish further the safety and effectiveness of these forms of intervention' (DH Steering Group 2008: 25). Whilst RCT could be thought essential for the *further* establishment of safety and effectiveness without being thought essential for establishing the efficacy of a CAM product, reducing the need for RCTs and then claiming that they are essential for establishing effectiveness sounds contradictory.

In addition, looking at what CAM researchers had to say about complementary and alternative ways of knowing and researching, there appears to be a high degree of methodological and theoretical conservatism in the writings on research ethics (Ernst 1994, 1996, Van Haselen 2006, Tilburt and Kaptchuk 2008), including, for instance, a straightforward application of the four bioethical principles of Beauchamp and Childress (autonomy, justice, beneficience, non-maleficience) as a basis for research ethics (Ernst 1996).[12] Social scientific and in particular science and technology studies work on CAM seem by far more critical of how knowledge is researched, regulated, and marketed both in RCT and in CAM contexts (Adams 2002, Kim 2007). In other words, whilst there could be a window of opportunity for more critical distancing from the mainstream model of building and governing research, in academic CAM journals, for instance, what one finds is rather a repeating of the well-rehearsed axioms of mainstream biomedical and bioethical thinking (Cohen and Schacter 2004, Mills 2001). As often is the case in legitimation through regulation, when one might expect to see alternative regulatory principles and ethical frameworks, what one gets is rather the reinforcing of mainstream norms.

V Resistance or compliance? Randomized controlled trials and their ir/relevance to CAM

In 2000, the House of Lords Select Committee on Science and Technology stated:

> Very little high-quality CAM research exists; reasons for this may include: a lack of training in the principles and methods of research; inadequate research funding and a poor research infrastructure within the CAM sector. Another contributing factor may

be methodological issues, with many CAM practitioners believing that conventional research methods are not suitable tools with which to investigate CAM.

A major implication of the 'regulatory objectivity' referred to above is medicine's normative commitment to the RCT as gold standard for both conventional biomedicine and CAM (Cambrosio *et al.* 2006, Moreira and Will 2010).

Still CAM researchers and practitioners have long highlighted the differences between biomedical and CAM knowledge, and complained about the limits and inadequacy of biomedical 'evidence base' methods to evaluate CAM therapies. At the outset, CAM researchers and practitioners sometimes use 'terms and ideas that are not easily translated into Western scientific language' (Zollman and Vickers 1999: 695). They have advocated a 'methodological pluralism' (Callahan 2004, Cohen 2003) to account for the epistemological diversity that characterizes medical knowledge broadly understood, including different forms of CAM. To them, biomedical research methods – including their gold standard, the randomized controlled trial – despite adequately testing biomedical treatments and drugs, are ill suited to properly assess many CAM therapies.

In order to prove its efficacy and effectiveness under the terms of modern scientific standards, research in CAM must often stay in synch with the dominant scientific paradigms of the time, and science's own theoretical conservatism. Within the scientific paradigm, researchers in CAM thus often have to proceed against these hierarchies of evidence, and literally reverse the normative order of biomedical testing. For instance, the biomedical investigation of a drug usually proceeds from chemical and animal experiments first, then moves on to clinical experiments. In order to align themselves with these biomedical conventions, some researchers in Korean medicine and Chinese medicine, for example, have translated their observations and anecdotes, in other words their clinical evidence, into chemical and animal experiments (Kim 2007: 871, Lei 1999). By doing so, these CAM researchers attempt to show the scientific relevance of their alternative, so-called 'cultural' knowledge capital to the biomedical community, whilst at the same time building on that biomedical community's own cultural tradition.

The RCT gold standard also shows its epistemological limitations if we further problematize the binary that posits CAM's personalization of medicine in opposition to the standardization of Western biomedicine. For instance, a temporary look at what CAM and mainstream medicine have in common, rather than at what sets them apart, can highlight a misalignment between the RCT and what it is cut to measure in both CAM and mainstream medicine. It may not be possible to translate faithfully the long-term clinical and experiential evidence developed in traditional and indigenous forms of medicine into scientific knowledge through a short-term RCT. But the RCT is not limited solely with respect to assessing CAM. Analogies have been drawn in this sense between CAM and the medical specialization of surgery. To assess the validity of surgery, it is not advisable to rely on clinical trials; instead, it needs to be experienced, that is, done again and again, hands-on, as well as taught and observed by peers over many years (Institute of Medicine 2005). In surgery, medical value and knowledge is attributed to a specific person, healer or professional, who performs the therapeutic act in question. In the field of surgery, the same procedure done by an experienced surgeon is not the same as by any other surgeon (Institute of Medicine 2005: 126). A given procedure, which can be scientifically proven as efficacious, might be effective only if a specific, experienced surgeon performs it. This is likely to also be the case with many CAM therapies. The CAM–surgery analogy further shows the slipperiness of the binary between CAM and science as they are ordinarily understood.

At this point, it is worth having a look at state-sanctioned hierarchies of evidence, which highlight the issues of the difficulty of differentiating biomedical knowledge from CAM knowledge,

and the limits of evidence methods to trace such boundaries. The hierarchies of evidence can also offer a point of entry for opening a larger debate on the relevance of finding a scientific basis for CAM.

State-sanctioned hierarchies 'rate the strength of a body of published data on a specific test or treatment', for the purpose of providing 'recommendations' for the use of 'preventive interventions in office-based clinical practice' (Institute of Medicine 2005: 94–5). Clinic practitioners, health organizations, and 'patients' or 'payers' tend to pay close attention to them. In *CAM in the United States* (2005), the Institute of Medicine (IOM) discussed how these state-sanctioned hierarchies of knowledge get negotiated and used. In the UK, according to the National Health Service's Centre for Evidence-Based Medicine, the hierarchy of evidence depends on 'the study design, the number of studies in the body of evidence, and the consistency of study results' (Institute of Medicine 2005: 96). The UK hierarchy of study designs suggests the following descending order:

> the combined results of several randomized controlled clinical trials (RCTs) receive the greatest weight in evaluating treatment effectiveness. The results of a single, well-designed RCT is given the next greatest weight. The combined results of observational studies or other non-RCT study designs comes next, followed by case series or anecdotal reports, and professional judgment or consensus.
>
> *(Institute of Medicine 2005: 96)*

By contrast to the UK hierarchy, the US Preventive Services Task Force (under the Agency for Healthcare Research and Quality, Department of Health and Human Services) does not hierarchize methods per se: 'it does not use a hierarchy of study designs ranging from the most powerful (randomized clinical trials) to the weakest (case series)'. Instead, it uses the generic characteristics of a study (e.g. 'well designed') (Institute of Medicine 2005: 94–5). In theory, this would means that a rigorous, 'well designed' case series, if suited to evaluate a given treatment, could rank high in the hierarchy. In addition, the hierarchy is described as a 'hierarchy of rating of the strengths of recommendations' rather than of evidence.

In another report, the Institute of Medicine (2001) explained how the distinction between treatment effectiveness and treatment efficacy can affect levels of evidence. Whereas efficacy refers to the ability to produce measurable desired medical results in 'experts' hands' – that is, in laboratories or in controlled contexts like the RCT – effectiveness refers to this ability in the daily routine practice of medicine, with unselected clinicians and patients. In other words, efficacy is about what a treatment *can* do in ideal circumstances, and effectiveness is what it actually *does* in daily use.[13] In the milieu, it parallels the distinction between explanatory studies (focused on efficacy) and pragmatic studies (focused on effectiveness). Namely, the IOM states that, if evaluating treatment effectiveness, 'the results of a single well-designed outcomes study should be considered to be as compelling as the results of a single well-controlled randomized trial' (Institute of Medicine 2001). This modulation by the IOM on levels of evidence, induced by the efficacy vs. effectiveness distinction, highlights the methodological need to examine the practical and subjective aspects of treatment. This could be read, in principle, as an approach more sympathetic to CAM. However, efficacy and effectiveness are understood as not exclusive of each other, but cumulative. Hence proving *both* efficiency and effectiveness can constitute a high threshold for CAM therapies to meet. For instance, a narrow study of physiological value (efficacy) of a CAM technique or treatment would say little about its effectiveness in real practice, although it could still produce a body of evidence that would give it credit (see Weisz 2011). It has been noted that, because of the placebo effect, any non-efficacious technique or

treatment could be found to be effective in certain situations (UK Select Committee on Science and Technology 2010). I cannot provide here a full account of the power, complexity, and mystery of the placebo effect (Harrington 1999), but the fact that it applies to both CAM and mainstream medicine further erodes the strict binary between the two.

The state-sanctioned hierarchies of evidence also shed light on the limitations of the gold standard of biomedical knowledge as a measuring instrument for *both* biomedical and CAM therapies and treatments. Read carefully, state-sanctioned hierarchies support a moderate form of 'methodological pluralism' (Callahan 2004, Cohen 2002–3; see also Welsh *et al.* 2004). They back *measuring* tools and *measureable* therapies that stand outside of the highly controlled contexts of laboratory science. In addition, they show how under the normative conditions of evidence-based medicine (Weisz 2005, Cambrosio *et al.* 2006, Moreira and Will 2010), even mainstream medicine can be, as we saw in the case of surgery, closer to CAM than we might think. In this sense, the hierarchies contain built-in openness to CAM, throughout explicit and implicit analogies with non-CAM knowledge.

Seen in the context of the state–law–science nexus, they indicate that the state is, in principle, less directly hostile to CAM knowledge than some accounts might suggest, and they even highlight potential ammunition for those who wish to push a regulatory and scientific agenda for CAM. This is especially true given that the nexus is itself contestable and contested.

VI Avenues for recognition? CAM research and its nexus with the state

In the UK in 2000, the House of Lords Select Committee on Science and Technology emphasized the need for a stronger scientific research base in CAM, especially in relation to efficacy and safety of CAM. Further, the Committee had explicitly stated that:

> [m]any CAM therapies are based on theories about their modes of action that are not congruent with current scientific knowledge. That is not to say that new scientific knowledge may not emerge in the future. Nevertheless as a Select Committee on Science and Technology we must make it clear from the outset that while we accept that some CAM therapies, notably osteopathy, chiropractic and herbal medicine, have established efficacy in the treatment of a limited range of ailments, we remain sceptical about the modes of action of most of the others.

Ties with the state can be institutional: state funding for research; education training within recognized state institutions; 'legislative recognition, incorporation in various health policies, insurance coverage' (Iyioha 2009). They can also be less immediately tangible and more directly related to the knowledge base: informing state policies, being recognized as experts by tribunals, and slowly attracting the attention of public and private research funders and sponsors (cf. Pressman 1998).

The historian of medicine George Weisz is interested in understanding what exactly makes a 'therapy convincing in one national context and not in another' (2001: 451). In his work on the therapeutic use of thermal waters in twentieth-century France, he notes that students of regulation and professionalization of health practices often see, with good reason, power relationships and the market as the main drivers for regulation and professionalization. However, he pointedly warns that we should not forget the critical impact of medical and scientific validation itself, that is, not necessarily scientific validity (Iyioha 2011, Casey and Picherack 2001), but debates *on* scientific validity. 'Battles over the infusion of scientific medicine' in CAM is thus part of the fight for their legitimacy (Welsh *et al.* 2004: 217).

Further, Weisz (2001) highlights the usefulness of 'specialization' in national debates on the legitimacy of a field of knowledge. In the context of French debates over the legitimacy of hydrology, and over whether spa and thermal waters treatment should be covered by national health insurance, for example, Weisz points out that specialization broke down broad claims and categorized them into different expert claims. In this case, specialization, by reducing the scope of claims, made them more convincing for clinicians, who tended to be sceptical towards general, grand statements: 'It is perhaps the very excess of these successes that awakens our mistrust to some degree', a doctor was reported to write about hydrology in 1911 (Weisz 2001). In other words, claims that are carefully tailored, toned down, modulated, and coming from a restricted specialist field would be more convincing.

'State law's espousal of science' (Santos 2002, Iyioha 2011) is, to many, critical to the history of exclusion of alternative knowledge systems, whether within or outside the health care domain (Iyioha 2009; see also Polich *et al.* 2010): 'Historically, state law has been known to espouse the dictates of science, and science, bolstered by the force of law, has been deployed as a tool of exclusion of nonwestern medical norms', writes Iyioha (2011: 8; see also Cohen 2004). The emergence and current domination of evidence-based medicine (EBM) further consolidated an epistemological commonality between law and science which goes back as far as the seventeenth century: a 'concern with degrees of certainty or, in more modern terminology, probability' (Shapiro 1983: 168), manifest in 'emphasis on the grading of evidence on scales of reliability and probable truth' (168). As an enveloping, encompassing paradigm, EBM is more controversial than biomedicine: its goal is to trim down as much as possible what it calls 'biases', that is, any knowledge that is intuitive and unsystematic (EBM Working Group 1992, as cited in Micollier 2011; see also Timmermans and Berg 2003). Further drawing on Iyioha, these current conditions mean that science 'sits at the root of the efficacy, safety and regulation debate on CAM' (2011: 8), and that state validation of CAM – via political, economic, statutory, and judicial recognition – and scientific validation go hand in hand. Those who pursue CAM research and work at situating CAM within the large domain of scientific research are at the forefront of this problem.

There are, however, ongoing debates about whether CAM therapies can be recognized unless they can demonstrate that their knowledge passes scientific evidential tests. Willis and White (2004) on their part, rather speak of 'clinical legitimacy'; to them, the patronage of therapy (like that of Prince Charles for alternative therapies) and the loyalty of consumers willing to pay for CAM could outweigh scientific legitimacy as a basis for 'politico-legal legitimacy' (58).

In a positivist fashion, Casey and Picherack acknowledge that 'formal bureaucratic organizational status' clearly fosters 'credibility with the dominant structures of the day' (2001: 69). CAM research generally tends to lack such infrastructures. Building such institutional arrangements, and skilful handling of the legalistic language of guidelines, flowcharts, codes of conducts and the like, constitute powerful tools of legitimation. With its mimicking of the state's language and audits, the pharmaceutical sector offers a particularly telling illustration (Petryna 2007, Jacob and Riles 2007). In addition, and although it has been somewhat overlooked, what makes a certain type of medicine (or any type of discipline for that matter) flourish and look successful in a particular state is also its main proponents' flair and agility at institutional and bureaucratic politics and their ability 'to schmooze and negotiate with government bureaucrats' (see Riles 2012). This last point makes explicit that CAM is, like other bodies of knowledge, shaped by institutional and bureaucratic logics. Its knowledge is purportedly alternative and distinct. However, as we saw above, its approach to regulation tends to mimic that of mainstream biomedicine. Why is that so? Could it be different?

VII Concluding thoughts: alternative regulation?

As highlighted above, recent calls by medical law academics for a more 'holistic' governance of research (Mason and Laurie 2013: 679) resonate with Stone and Matthews' proposal for holistic regulation of CAM (1996: 291). In the conclusion, I would like to explore what an alternative regulation of research could look like.

Recent works on knowledge practices by science and technology studies scholars and anthropologists (e.g. Timmermans and Berg 2003, Gusterson 2003, and Blum 2009) have documented a refreshing willingness to critically revisit current scientific research governance and research integrity frameworks. As I have discussed elsewhere (Jacob 2011), these accounts provide open-minded engagement with other modes of producing and regulating knowledge that do not fit with the current research governance frameworks.

To take one example, historian of science Mario Biagioli (2003) has discussed a practical alternative to current research governance norms stemming from his work not on CAM but on mainstream science. This radical departure from the current normative framework of research governance in the area of authorship comes from the field of particle physics. Biagioli explains how, in 1998, the Collider Detector at Fermilab (CDF) Collaboration[14] members appointed their own committee to draft bylaws that would regulate the CDF research project with respect to authorship, responsibility, and credit. The CDF regulated on the basis of a 'labor mentality' that accumulates work credit, and is in stark contrast with the 'originality mentality' that prevails in IP and in biomedical science (ICMJE 1997). Think, for example, of the impact on authorship of the following rule on parental and sick leave policies: for up to a year, a member can have his or her name appear on all publications produced, 'based on research they may or may not have directly contributed to' (Biagioli 2003: 270). CDF also puts forward corporate, rather than individual, definitions of authorship, credit, and responsibility. As I have discussed elsewhere (Jacob 2011), Biagioli saw the possibility to redefine these regulatory concepts with respect to research because of the specific 'disciplinary ecology' (2003: 273) of particle physics: for example, highly bureaucratic internal structure, small size, people working together in the same site (in contrast to clinical trials in biomedicine, where co-authors may never meet each other).

I find the example of the CDF useful for thinking about CAM research regulation because of the boldness with which particle physics researchers and research administrators rewrote mainstream regulatory concepts, establishing their discipline as a genuine alternative. The example is also useful because CDF shows that research governance norms – in this case, norms of authorship – can hardly be universal, and ought to be linked to the 'disciplinary ecologies' of fields and practices. Although much CAM research derives out of insights from mainstream scientific research, I suspect some forms of CAM research have many distinct features it could build upon while thinking about its own norms of research governance.

Hence the importance of recalling Porter's (1989) critical point, on the importance of examining the self-representation of CAM, in light of CAM practices. There is currently very little CAM-ness with respect to research governance per se. Explanations for this could be that CAM research is under-funded and barely surviving, and that in this context, proposing a radical, transformative alternative is a luxury the CAM research community cannot afford. At the CAM conference *Regulation and Professionalization in Complementary and Alternative Medicine* in May 2011, I asked the question: Why do CAM researchers not take a more radical, alternative approach to research and, for example, rewrite codes of conduct for research like the CDF particle physicists did? The retort I received was that CAM researchers were less interested in creating new ways of thinking about research and regulation than about getting standard EBM to recognize them. This of course resonated with the 'old' problem of negotiating the tension

between innovation, recognition, and regulation. Nevertheless, one cannot help but wonder whether in the future we will witness even more ethical–legal audacity on the part of those who practise and research alternative ways of caring and knowing.

Notes

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2 Since 2010, I have been conducting ethnographic fieldwork for the quarterly Forum meetings of the Committee on Publication Ethics, and doing legal and archival research of General Medical Council research misconduct cases.

3 For an interesting analogy, see the discussion of Riles (2002) on alternative dispute resolution and its immunity to critique.

4 Already in the nineteenth century, the move towards alternative to regular medicine ('fringe medicine') was motivated by disappointment that orthodox medicine caused. Roy Porter (1989) describes how CAM in Europe were perceived as a radical dissent and presented themselves as 'the antithesis of an orthodoxy that could be accused of being no less therapeutically foolish then ethically and professional corrupt'.

5 2004/3391, pursuant to the European Communities Act 1972.

6 The US Office of Research Integrity, the Danish Committee on Scientific Dishonesty, and the Norway National Commission for the Investigation of Research Misconduct.

7 For instance, the joint conference on misconduct in 1999 in Edinburgh, the Research Integrity Futures Working Group (2010) and the Research Integrity Concordat (2012).

8 COPE is an international, London-based advisory body for editors as to how to handle cases of research and publication misconduct, including a forum for editors and publishers of peer-reviewed journals to discuss all aspects of publication ethics: http://publicationethics.org.

9 Instead an annual report (which takes the form of a letter) mentions there were 15 this year. We do not know, however, how much research activity is occurring in the fields covered by the Complementary and Natural Healthcare Council.

10 Also known in the sociology of science as Mode 2 knowledge (Nowotny *et al.* 2001).

11 Directive 2004/24/EC.

12 Interestingly, in an editorial on the issue of research misconduct, the editor of the journal *Complementary Therapies in Medicine* committed to deal with the problem 'on a synergetic basis', a surprising, if not alternative, turn of phrase, admittedly rarely found in mainstream writings on research misconduct (Van Haselen 2006).

13 The IOM considered the importance of looking at how evidence fares in practice, and thus described the components of what an 'effectiveness RCT' study would include:

- light patient exclusion criteria;
- conducted in a range of treatment settings;
- treatment provided by the kinds of providers who would provide treatment in non-study settings;
- no elaborate data collection (e.g. extra lab test or imaging studies);
- analysis done on 'intention to treat' basis; and
- random assignment with one or more control groups.

(Institute of Medicine 2005: 96)

14 CDF is a consortium of institutions that provide staff and support the Fermilab laboratory. Potential members of CDF are selected by their home institutions to work at Fermilab for a specific period.

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