

Will the Real Expert Please Stand Up?

Power, Credibility and Expertise in Medical Discourse

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In 2006, Stephen Tower was 49 and an endurance cyclist, and a poster child patient for a metal on metal (MoM) hip resurfacing (ASR). As an orthopedic surgeon himself he carefully chose the particular device and surgeon for his procedure. However, by the spring of 2007, one year after the ASR, all was not well with his hip. There was pain after long bike rides, difficulties exercising at altitude, balance issues resulting in falls and bike crashes, and a blood cobalt level was 40 times the Biologic Exposure Index (BEI). A “normal” blood cobalt level is 0.2 parts per billion (ppb). Parts per billion and micrograms per liter (mcg/L) units are interchangeable. One year post ASR, Tower’s level of 40 ppb was 200 times normal.

Six months later Tower was transiently disabled by a “mood disorder not otherwise specified.” This problem came on coincidentally with tinnitus, mild deafness, spatial disorientation and sleep apnea; he needed a CPAP machine at night, was breathless with minimal exercise, and was requiring multiple medications and weekly counseling to manage his “mood disorder.” Several months later, he discovered a new tremor and a lack of coordination in his non-dominant right hand. Due to his hip pain and dysfunction alone, it was clear by November 2009 that the ASR needed to be redone.

When his surgeon placed the spinal needle for his revision anesthetic in November of 2009 he collected some fluid. Tower's CSF cobalt level was the third highest ever published (Tower 2010). The others on the podium were deaf, blind, and in all likelihood dumb. (Steens, *et al* 2006). His revision surgeon found an untended crankcase of metallic sludge about the ASR and wear of one sector of the socketing 100 times that which was expected. Tower had lost the ligaments that hold a hip reduced because of Adverse Local Tissue Reactions to Metallosis (ALTRM), a problem that would result in nine dislocations of his otherwise well functioning ceramic-plastic revision hip.

After the removal of his MoM hip, Tower's mood disorder, tremor, vision problems and other symptoms disappeared. At this point, Tower's suspicions that cobaltism from his MoM hip had been the cause of neurological disorder seemed confirmed and he set out to add this information to the discourse on MoM hip complications. His resolve hardened when he revised the only patient that he had implanted with an ASR. His cobalt levels had peaked at 25 times the BET and he had developed all of Tower's maladies to a lesser degree. Now Tower had a series case after case.

The manuscript of the "series" submitted to the American Journal of Bone and Joint Surgery was not warmly received at first. The three anonymous "peers" were split as to its merit and the adult reconstruction subsection editor was a consultant for DePuy, the manufacturer of the ASR. The paper seemed fated to a death by a thousand resubmissions until a direct appeal was made to the editor in chief, a pediatric orthopedic surgeon without financial interests in the ASR. He allowed Tower to replace edited content; and the delay in publication also allowed for the inclusion of an independent laboratory's analysis of Tower's explant. The report was

published online in October of 2010, three months after the ASR's formal recall (Tower, 2010). It was submitted in March or April.

Its publication was accompanied by a commissioned commentary by a Vice President of the American Academy of Orthopedic Surgeons (AAOS), Dr. Joshua Jacobs. This is an unusual, perhaps unprecedented, for the governance of the AAOS to be involved in critiquing a scientific paper. Jacobs' work partially underpinned the reintroduction of the metal-metal hips and was largely done on via industry funding and consultancy fees rather than through royalties on a specific implant. At the time of the commentary Dr. Jacob's declared conflict of interest (COI) included consultancies and stock options with multiple companies involved in the development and marketing of the MoM hips and financial support of his lab. Dr. Jacobs contended that arthroprosthetic cobaltism from a MoM hip was likely extraordinarily rare because about a million had been implanted and Tower's report was the first published. (Jacobs, 2010)

Shortly after the paper and Dr. Jacobs commentary were published an AAOS sponsored a Webinar addressing the complications of MoM hips was held. The surgeons that organized the event and the surgeons on the panel *all* had notable MoM hip COI's. One was Dr. Jacobs, another Dr. Schmalzried (the design surgeon of the ASR), and the third was Dr. Cuckler who was an advocate for Biomet's MoM's hip products. (Cuckler, 2005) The program focused on the periprosthetic complications of chrome-cobalt metallosis that were being increasingly recognized and largely dismissed cobaltism as being a realistic concern. During the mandatory disclosure of potential COI's the surgeon panelists noted that they were industry consultants and received royalty payments for the sales of MoM hip implants but these relationships had no bearing on the topic being addressed.

It took the good offices of Senator Begich to obtain a contact for Tower within the FDA. Dr. Yustein explained to Tower that he was unqualified to be “expert” in the FDA’s eyes because he did not consult for industry and he had not been forwarded to the FDA by the AAOS as an expert. The means by which the metal-metal hips got through the FDA’s abbreviated and expanded pre-market approval process was now apparent. When he reported back to Senator Begich that the FDA relied on entirely industry for “expert” opinion about the safety and efficacy of MoM hip replacements he responded that his office could not get involved in “scientific” disputes.

Tower was determined to get the word out at the 2013 meeting of the AAOS. He submitted three scientific papers, one Instructional Course Lecture (ICL) proposal, and one Symposium proposal, all addressing metal-metal hip complications. It was about 100 hours of work, mainly to contact candidates to be on the panels for the symposium and the ICL. He eventually assembled a world class faculty without significant COIs. Everything was turned down by the hip program committee. Three quarters of member of this panel had declared COI with arthroprosthetic companies with a stake in MoM hips. The selected panel for the symposium was largely a repeat of the previous year including Dr. Schmalzried and Dr. Jacobs. The moderator was Dr. Lombardi, a Biomet design surgeon and former metal-metal advocate. He was also the President of the Hip Society and the chairperson of the hip program committee that had rejected Tower’s five submissions.

Several months ago a European researcher that Tower met at the 2012 AAOS meeting requested that he review her manuscript on the systematic survey of their 600 hip resurfacing patients for the symptoms of cobaltism. It was a large undertaking and a surprising one given that her center had hitched its star to hip resurfacing. They found that patients with blood cobalt

levels of > 10 mcg/L experienced mood, cognitive, and sleep disorders at a rate greater than those with lower levels. Once cobalt levels were above 20 mcg/L these problems became frequent. Although tinnitus and deafness were common presentations of cobaltism these symptoms were not as specific as mood instability, cognitive changes, and disordered sleep as sentinel symptoms of cobaltism because tinnitus and deafness are so common in the arthritic population. The manuscript noted that they had confirmed the diagnosis of cobaltism in 4 of their patients, only one of these patients was the subject of a prior publication (Van Der Straeten, *et al* 2006).

The manuscript was submitted to Clinical Orthopedics and Related Research (CORR). There have been about a hundred publications in CORR relating to metal-metal hip technology. Those papers published before 2008 are generally favorable to the technology, were written by a cabal of surgeons vested in the technology, industry funded, and the peer review of these papers was likely done by surgeons with similar COI as the authors. Tower gave the European paper his highest recommendation. The other three reviewers were contrary, as was the editor. The paper was rejected without an option for revision. The fundamental cited flaw in the paper was that it did not include a control group.

Tower then wrote a letter to the editor of CORR pointing out that few if any of the approximate 80 papers published in CORR that supported metal-metal hips contained control groups and that most of the 600 patients in the European study had blood cobalt levels of < 5 mcg/L and that this group was an acceptable control. He requested that CORR provide him with the declared COI of the three reviewers. The editor was offended—and argued that Tower's request violated the spirit of blind peer review. Indeed, CORR does not so much as have its peer reviewers submit disclosures of potential SICOI! The paper remains unpublished today.

Dr. Tower's struggle highlights the ways in which mutually reinforcing structures of power, especially within medical specialties, can render claims of conflicts of interest meaningless. We use Dr. Turner's case to illustrate the way in which the integration of medicine-as-science and medicine-as-industry (what we shall term, following Habermas (1984), the "colonization" of medicine) deprives members within and outside of a professional community of a frame of reference from which claims of epistemic authority can be fairly and accurately adjudicated. In such a context, the reliability of a speaker's claims is judged almost exclusively in terms of the credibility of the speaker, whereas the validity of the speaker's truth-claims go unexamined. In medicine, as in the sciences generally, the credibility of the speakers is often generated through the authority of "expertise." However, in colonized medicine, expertise is increasingly defined in industrial terms in which significant techno-industrial success becomes the hallmark of expertise. The industrialization of medical expertise creates a methodological paradox in scientific inquiry: those who have the most expertise (and thus guide the inquiry) are those who are least likely to be objective. We argue for a more inclusive and normative account of expertise that emphasizes both technical achievement and the virtue of impartiality.

The Colonization of Medical Discourse

Medical inquiry, like all scientific inquiry, is essentially a discursive practice as it involves the development and evaluation of truth claims between speakers. As rooted in the evaluation of truth claims, such a discourse, to be rational, must be guided by norms and procedures by which speakers offer justifications for their claims based on the forceless force of the better argument oriented towards a consensus of fellow discursive partners. These norms include transparency,

publicity of evidence, appeal to the best explanation, freedom from coercion, and a commitment from speakers that they speak truthfully, sincerely and that they evaluate the claims of others impartially. When properly proceduralized and institutionalized, such discourses reflect the “communicative rationality” that is at the heart of discursive legitimacy for modern, pluralistic and post-conventional societies (Habermas, 1984, 1986, 2000).

Scientific discourse, like many specialized sub-discourses in society, differs from moral and political discourse in that while it is in principle public and open to all, the knowledge and skill requirements for rational and informed evaluation of truth-claims requires that those with specific training, skills and experience assume an authorized status in the discourse. While the role of authority has been the grist of many postmodern critics of science, when properly constructed the use of authority in a truth-oriented discourse is by no means an epistemological barrier. By limiting, and to some degree privileging “uptake” to those speakers who have the requisite skill sets to adequately evaluate scientific truth-claims, discourses in the sciences are better able to sort out the “signal versus noise” problem that plaques more open discourses such as the discourses on morality, aesthetics and politics. Moreover, the use of experts is often a reliable source of knowledge production and informed evaluation within and at the borders of scientific discourse. Journal editors rely on experts in a particular field to review the importance and scientific validity of manuscript submissions; conference organizers rely on peer-experts in the same way. Through peer review at the journal and conference level, as well as through academic appointments, expertise plays a significant gate-keeping role in the flow of information within the discourse. Likewise, experts play an essential role in advising laypersons on the best science of the day. Regulators, policy-makers, judges, juries, journalists and even bioethicists

routinely rely on scientific experts for an informed evaluation of the current state of scientific knowledge (Goldman, 1999).

Again, our view is that when properly structured, reliance on experts is a reliable veritistic practice. Experts are often in the best epistemological position to generate true claims and to evaluate the truth-claims of other speakers in the discourse. However, the use of expertise in scientific discourse creates a delicate balance between authorization and exclusion. When rational, authorization in scientific discourse improves the quality of inquiry. However, when corrupted, authorization in scientific discourse can become a mechanism for marginalization of relevant speakers, arguments, evidence and perspectives. In this latter case (and these are the cases that critics of scientific discourse focus on) the use of authority in science undermines the rational legitimacy of the discourse and degrades the epistemic quality of the inquiry. Our view is that Dr. Tower's case illustrates that various structural changes to the medical discourse has created a skewed model of expertise. These changes we term the "colonization" of medical discourse.

In modern societies, veritistic discourses structured around communicative rationality are by no means exclusive. In economic, bureaucratic and to some degree legal discourses, open consensus-seeking forms of communication are complemented, or entirely replaced by, what Max Weber called *zweckrationalität*—instrumental or strategic rationality based on the application of administrative or bureaucratic power (Weber, 1905). In the context of many social systems, rationality is constrained to efficiency calculations based on given ends that themselves are not subject to evaluation. In bureaucratic contexts for example, claims between speakers are often not aimed at consensus via the forceless force of the better argument, but resemble instead

commands issued from superiors to subordinates based on strategic calculations of the imperatives of the organization.

The distinction between communicative and instrumental rationality is an analytic as opposed to an empirical distinction. Real flesh and blood forms of social organization always have elements of both communicative and instrumental reasoning. Bureaucracies have numerous levels of discourse in which individuals exchange reasons about truth claims aimed at rational consensus. Likewise, scientific discourse would be impossible without the efficient use of institutions and resources that make the meaningful exchange of ideas possible. However, there are also important differences between various kinds of discourses. Because some discourses (science, morality and politics) are truth-oriented discourses, the use of strategic rationality and administration power in those discourses must, if the discourse is to be legitimate, be steered by communicative rationality and communicative power. When a truth-oriented discourse comes to be steered by strategic rationality and administrative power, that discourse has become *colonized*.

A colonized truth-oriented discourse is one that relies on a superficial commitment to procedures and institutions that concretize communicative rationality, however, the operation of those procedures and institutions are actually steered by strategic rationality in services of the steering mechanisms of money and/or administrative power. What makes such a discourse *colonized* is that the effects of communicative rationality (communicative power *via* rational legitimacy) is harvested while the substantive commitment to communicative rationality is disposed. The result is a discourse that is no longer truth-oriented, but enjoys the social power and influence of one that is.

Our view is that medical discourse in the United States, especially in specific subfields such as pharmacology and orthopedics, have become increasingly colonized by instrumental rationality and administrative power in the service of economic interests. Medical discourse in the United States has always involved a certain measure of partnership between science and industry. In a free market society, most therapies are ultimately made available to patients through market mechanisms—the research, development, production and distribution of health care resources via private, for profit, enterprises. However, a shift has occurred over the last generation in which industry support and influence has increased dramatically (IOM, 2009). There are various reasons for this including, and perhaps especially, the 1980 Bayh-Dole Act which allowed institutions to patent discoveries that resulted from federal research (before that time the federal government would hold such patents). Institutions, such as universities, were then able to collect licensing and royalty fees by licensing other entities (i.e. industry) to develop those discoveries. The Bayh-Dole Act, and other developments in biotechnology, led to a significant increase in the funding of research by industry (Schacht, 2008) In 1977, industrial funding counted for 29% of support for clinical and non-clinical research in the United States (Read and Campbell, 1988). By 1989 that proportion had grown to 45%, and by 1995 it had swelled to approximately 60% (IOM 2009). Today industry is the largest source of funding for biomedical research in the United States. Likewise, a 2006 survey of medical schools and teaching hospitals found that 67% of academic departments had relationships with industry (Campbell, *et al* 2007) and a 1998 survey found that 43% of academic scientists the most research intensive universities received research related gifts from industry. 66% of those scientists believed those gifts were “important” to their research. (IOM, 2009).

The transition from what we call “public” medicine to “industrial” medicine has numerous advantages and has proven to be beneficial in many ways for scientists, industry and consumers. For instance, academic researchers with industry ties are more likely to be involved in start-up companies, more likely to have patents, and more likely to have products on the market. Importantly they also tend to publish more articles in peer-reviewed journals than their peers who lacked industry relations (IOM, 2009).

However, there are important ways in which industrial medicine skews medical discourse because speakers in the discourse are increasingly guided by economic imperatives and administrative power. Scientists in the life science are more likely to have their work result in “trade secrets” which will not be shared with other speakers of the discourse for study and evaluation. Academic researchers with industry ties are also more likely to delay publication of scientific discoveries to allow for their antecedent commercialization. Academic researchers with industry ties are more likely to rely on data analysis provided by industry statisticians and lack full access to all the data of the study. Studies funded by industry are much more likely to support industry products; and studies that do not are much more likely to go unpublished. Some studies have found that researchers with industry funding suffer from significant confirmation bias of industrial products. This bias includes reaching conclusions favorable to industry even when such conclusions are not supported by evidence and “scrubbing” published studies so that they appear more favorable to industry. (IOM, 2009; Beauchamp, 1992)

As medical discourse devolves into an economic discourse, “expertise” becomes increasingly reliant on technical and economic achievement and becomes detached from its normative underpinnings within veratistic discourse. Expertise within “industrial medicine” is defined according the achievement of particular instrumental goods-- patents, grants and

contracts are constitutive of expertise on this model. To be an expert is to achieve these self-perpetuating ends, where the interests of the expert, university or company are served by isolating knowledge and increasingly making one's self indispensable in the search for medical knowledge. To be an expert is to make the aggregation of knowledge possible. An expert gathers the tools of knowledge, stamps them with a particular identity, and controls how knowledge will flow, to a lesser or increasingly greater degree, from that moment forward. Control, power and recognition are the essence of expertise in "industrial medicine."

Truth and problem-solving are not irrelevant on this model of expertise. It could be countered that even if expertise in "industrial medicine" afford certain kinds of power, that power is earned through observable test results within medical science. The right to a patent is grounded in the ability to demonstrate that one has made a truly novel product or improvement. The patent must be able to resist challenges which sometimes turn on shared agreement about the worth the things patented. Surely, this is a kind of truth. Scientific papers in medicine – as long as they are not based on falsified results or the use of deceptive practices – often depend for their legitimacy on reproducible results and their explanatory power for scientific problems. Practical results are not inconsequential in medicine. Are patients actually healed or helped by a particular drug or treatment? The degree of improvement or harm to patients can be theoretically measured and used to hold certain players in industrial medicine accountable. Lawsuits involving the drug Vioxx and others can be used as examples. It is in the best interests of scientists, doctors and companies alike to create products that work. It is only reasonable, then, for expertise to map closely onto those who solve problems and produce positive results with which most can agree. Unfortunately, this conclusion does not necessarily follow.

It is critical that experts appear to be centrally engaged in the search for medical truth. This, at least, is clear. By in large, the public trusts that medical science works in its best interests. The trust they feel is an extension of trust assumed in the doctor-patient relationship. After all, many medical researchers are clinicians as well. It is natural for the trust regarding one role (physician) to be transferred to a larger role (physician-researcher). Impartiality is the foundation of science in the West. Even for those who believe that the elimination of all human bias is impossible, the core virtues of the scientist defined around objective veritistic inquiry. We expect impartiality to be the driving motivation behind medical science. Expertise in medicine science is expected to embody excellence in the search for impartiality. It must appear this way to retain legitimacy in the larger, public system.

Dr. Tower's case highlights the paradoxical nature of expertise in "industrial medicine". The gate-keeping function of expertise—when detached from the objectivity that is the normative heart of veritistic discourse—grants experts extraordinary influence in scientific discourse such that certain lines of inquiry—those critical of industry—are effectively marginalized. In their gate-keeping function within medical discourse, experts are strategically placed as journal peer reviewers, conference organizers and review boards, IRB boards members, and consultants for regulators. Again it is not unreasonable to rely on experts for these roles, however, in colonized medical discourse the concept of expertise has become dangerously detached from its normative underpinnings. Those most likely to produce the products that "baptize" one an expert—journal articles, patents, and products on market—are precisely those also most likely to suffer from substantial conflicts of interest and the potential (and real) loss of impartiality.

In the case of Dr. Tower's efforts to explore the dangers of cobaltism in MoM hips one sees how FDA, for instance, relies on experts on MoM hip replacements and resurfacing to assess the safety and efficacy of that product—however, many of the experts in this field have significant, and lucrative, ties to the very products they are evaluating. Likewise, in Tower's experience at AAOS 2013, the majority of a review panel selecting papers on MoM hip devices had similar ties to industry. The result—an entire slate of papers that supported the safety and efficacy of metal on metal hip replacements—and the exclusion of several papers critical of the product. Consider also the rejection by *Clinical Orthopaedics and Related Research* of the study on cobalt toxicity of MOM hips because the study lacked a control group. The same journal has published over fifty studies supporting the safety and efficacy of MOM hips despite the lack of a control group. Whether this last outcome was the result of conflict of interest is unclear because the journal does not even ask for disclosures from peer reviewers and thus makes no effort to screen out those with significant conflicts of interest.

The broad tolerance of, if not indifference to, conflicts of interest on the part of the experts in industrial medicine undermines the legitimacy of medical discourse. A veritas discourse can count as legitimate only to the degree that the truth claims of speakers can be made available to other speakers for impartial evaluation. In complex discourses this requires procedures and institutions that standardize and guarantee speaker access to other speakers and to the impartial evaluation of their truth claims. Typically, procedures such as blind and confidential peer review have typically been seen as providing such a guarantee (Goldman, 1999). However, as expertise in various fields of medicine becomes increasingly conflicted, certainly the appearance, if not the very practice of the scientific discourse becomes corrupted.

A NORMATIVE MODEL OF EXPERTISE

Our view is that the cobalt toxicity of MOM hips highlights a structural shift in the way medical discourse is conducted. The role of industry in medical research, particularly in orthopedic medicine, is greater than ever and has given rise to a model of expertise in which technical and academic achievement has become detached from impartiality and objectivity. In light of this, numerous critics in Science and Technology Studies and elsewhere have argued for the abandonment of the idea of expertise and the embracing of a “technological populism” (Collins, 1997; Fuller 1993;). We do not accept this view. Even in its compromised state, expertise in medical discourse has proven to be conducive to research and rapid advancement in therapies for patients (IOM 2009; Beauchamp 1992). We propose addressing the problems in the current model of expertise by arguing for a *normative* dimension of expertise. As key members of a veritistic discourse who are entrusted by members of the discourse, as well as by regulators, policy makers and the public at large, an “expert” is not merely a person with sophisticated knowledge and skill sets, but is also a person who participates in discourse in an *impartial and objective manner*. Understood normatively, the kind of expertise that should be sought out within medical discourse should take into account the conflicts of interest that a particular expert-candidate faces. By “conflict of interest” we mean: *A set of circumstances that would lead a reasonable observer to conclude that there is a substantial risk that the duties of the professional will not be honored due to the professional’s unique self-interest (e.g. economic incentive, reputation).*

Of course, someone with a conflict of interest might well be able to be impartial (Beauchamp, 1992; Davis 1982, 1993). However, just as published articles and patents are a *marker* of, and not constitutive of, expertise so too is the status of an expert-candidate’s conflicts

of interest. Operating under conflicts of interest is a marker of an increased probability of bias and thus a *decrease in one's expertise*, whereas operating free from such conflicts, all things being equal, is a marker of impartiality and thus the presence of at least one element of expertise.

Table 1 illustrates an index of expertise:

Table 1: Index of Expertise

	High (10-7)	Medium (6-3)	Low (3-0)
Technical Expertise	Numerous and influential journal articles, significant academic and professional appointments, key patents and devices on market	Average number of journal articles, important research or professional appointment, perhaps has patents.	Few journal articles; no academic appointment; no patents.
Normative Expertise	Few if any markers of bias or partiality;	Personal circumstances are such that there is some to moderate risk to the impartiality of judgment.	Significant conflicts of interest; key financial gain at stake; key professional reputation at stake;
Total Expertise	Total score from both technical and normative expertise. 20-14= high expertise; 13-6=moderate expertise; 5-0= low expertise		

Regulators, journal editors and conference organizers should seek out the best experts available. However, on this index of expertise the composition of those experts should change from the usual suspects. In industrialized medicine, “experts” rank highly on technical expertise but many rank rather lowly on normative expertise. On our view, this diminishes their total expertise and would make many of them moderate experts at best. Meanwhile, many “rank and

file” members of medical discourse, such as Dr. Tower, would rate significantly higher on our index of expertise compared to a technical model alone.

Dr. Tower’s commitment to the practices of impartiality gives him a fundamental claim to normative expertise. While bias and conflicts of interest signal a block to impartiality, transparency, openness, and the scientific pursuit and evaluation of data are definitive of impartiality and normative expertise. We see ample evidence of this pursuit in Dr. Tower’s work. With very little professional and institutional support, Dr. Tower rigorously documented the symptoms that he and a number of his patients experienced after receiving metal-metal hip implantations. On his own time, Dr. Tower meticulously created a database of objectifiable elements describing their cases. He developed a methodology for capturing and comparing what could be very interior and personalized experiences – including feelings of depression – into data point that could be known and analyzed by others. Blood tests confirmed or disconfirmed the presence of heavy metals in patients. Key indicators of inflammation were monitored. Magnetic imaging, and for some, surgical interventions documented the tragic destruction of hip tissue around the metal-metal implants. Dr. Tower’s data was gathered according to the widely-shared rules of scientific inquiry.

Dr. Tower’s work represents true normative expertise in that he has deliberately engaged with his colleagues as rational agents by presenting them with the data and requesting an open dialog about the harms he has documented. By relying on data, Dr. Tower makes use of a mode of investigation that is open to any rational agent with the knowledge and resources to test the data. Anyone can gather data and judge the matter for themselves. Anyone with the proper resources can attempt to confirm or disconfirm his hypotheses with their own valid tools and methods. Dr. Tower encourages his colleagues to do so. He has vigorously advocated for

greater testing of patients with metal-metal implants so heavy-metal blood levels can be publically tracked and correlated with problematic implants.

Dr. Tower has worked to share his data on a number of fronts, including repeated – and sometimes successful – attempts to publish and present his data on the national level. He has also been a fierce supporter of a national database for where data about the success and failure of implants could be collected and shared on a national level, and results would be shared with the surgeons who performed the original work. This kind of feedback, done with the proper respect for confidentiality, makes knowledge in this area possible. The data could exist and trends could be studied.

Dr. Tower's method here is in sharp contrast to those in the orthopedic leadership who have flatly rejected his attempts to rally the base and encourage his colleagues to gather more data for themselves. Here, Dr. Tower's claim is simply for his colleagues to recommend blood or other tests of their patients with metal-metal hip replacements to document whether or not damage exists. The leaders in his field have blocked this attempt by both limiting Dr. Tower's official conference appearances, limited his publications on this topic, and simply not advocating for the simple gathering of data themselves. His professional leaders and experts do not try to respond to the data that exists. They limit investigations and debate, and who can participate in the debate, rather than further the discussion. At this time, a national database tracking the success and failures of orthopedic implants does not exist in the U.S. The AAOS, Dr. Tower's professional society, shows little enthusiasm for the project.

Importantly, normative expertise is not a measure of the truth of one's data or hypotheses. Normative expertise *is* truth-conductive—especially if we take a long term view of knowledge

production: the features of normative expertise are ones that likely reveal the truth in a process of inquiry. This is a measure of a researcher's excellence as a participant in the veritasit discourses, and those are the practices of impartiality. It is possible that Dr. Tower's hypotheses regarding the causal links between metal-metal hip replacements and systematic consequences in many patients are wrong. That is less and less likely in many cases, but regardless, normative expertise captures the virtues underlying the pursuit of science, namely, impartiality. Such virtues will often lead to the truth, but not always.

It is reasonable to consider Dr. Tower's own personal bias in investigating the metal-metal hip implants. It is undeniable that Dr. Tower was initially motivated by his own negative experience with the implants. Even now, the ferocity with which he presses the AAOS to account for his data speaks of a more personal driving force. Surely, he has not sacrificed so much for the intrinsic value of scientific knowledge. Perhaps his personal experiences bias him to search for experimental correlations where none exist. Should his personal bias detract from his normative expertise?

Personal ties – even ones that are laudable in their own right – are potential impediments to impartial inquiry and more work should be done to distinguish between different levels of bias and how they threaten and erode normative expertise. To Dr. Tower's credit, he has been thoroughly forthcoming about the role his own experiences have played in his research. There is no attempt to hide this link. Whether due to an illness in one's self or one's family, personal motivations have a long history of inspiring progress in medical research. There are undoubtedly important differences in how personal motivations to seek justice or understanding through research effect an enterprise and how stock holdings, faculty positions, and other conflicts of interest effect researchers. Nevertheless, such personal bias may be grounds for having slightly

less confidence in Dr. Tower's normative expertise. Greater importance, then, is placed on his participation in the practices of impartiality. Dr. Tower's rigorous collection of data and attempt to subject his data to wide-spread critical evaluation places him in excellent standing. His data in addition to other independent studies of problems with metal-metal implants makes any dismissal of Dr. Tower's research due to personal bias unconscionable.

Normative expertise implies a dedication to data, transparency and impartiality in method, and actions that further inquiry and knowledge. Scientists commit themselves to the norms of a veritas discourse, and hence, participate in the kinds of practices that constitute impartiality. On one hand, this commitment is simply one of the constraints of the discourse behind science and medicine. Conflicts of interest that erode researchers' impartiality violate the norms of the discourse on which they depend as professionals. On the other hand, the normative pull of impartiality exists for scientists because they must seek and gain trust from one another and the public in pursuing their professional aims.

As mentioned earlier, many medical experts are also clinical providers. They request trust in nearly every facet of patient care. The wide differential of knowledge and experience between provider and patient places the patient in a particular position of vulnerability, the provider asks for trust even from a seasoned member of the medical community who assumes the role of the patient. In return for the patient's trust, the provider will respect her autonomy and care for her best interests. Respect for confidentiality and patient autonomy more generally are often approaches to medical care, rather than explicit contracts between provider and patient. In hundreds of ways, the provider assures the patient that the provider will govern herself according to the norms of ethical patient medical care. Patients divulge some of the most personal features of their lives, sometimes consent to care that will occur while the patient is

unconscious, and follow the advice of their providers, all on the assumption that the provider abides by this covenant between them. Medicine would be impossible without trust.

By failing to properly account for conflict of interest, industrial medicine violates the trust of patients and other members of the public on which it depends. The public buys medical products – or allows them to be prescribed for them – believing that the process by which the product is authorized is a scientifically valid one that looks after the patient’s interests. They believe the experts who participate in this process primarily conduct themselves according to the norms of impartial inquiry. They must trust this process. The level of expertise required to evaluate the product is beyond most members of the public. Even if they have the expertise, experimental trials require a system that few have the time and resources to organize. Here, financial transactions are part of the medical system, but even financial exchanges depend on a series of expectations about processes that validate the worth of the product. To have a provider’s seal of approval is usually reassuring, due again to relationships of trust.

In many cases, providers are also asked to trust that the proper protocols – including fair and accurate trials, assessments by numerous boards of review, and FDA approval – are honestly conducted and fairly reported. Most providers believe that conflicts of interest exist in medicine, but they must believe conflicts do not change the essence of this process. Providers’ initial requests of trust from patients depend on their truthful assessment of this process. Providers cannot, without violating their relationship with patients, recommend a product that they believe is not honestly tested and validated. They cannot simply prescribe a drug, hoping that the fundamentally conflicted system for drug testing produced a workable, useful product in the end. This is not the agreement between provider and patient. This is not the agreement between the public and its medical regulatory boards.

Conclusion

The case of cobaltism in MoM hips highlights the ways in which the procedures of the veritistic discourse of medicine can be colonized to serve economic imperatives. In our view, a key element of this colonization is the technical model of expertise that, in industrialized medicine, creates a feedback loop from economic power, research, regulation, and back to economic power. We counter this trend by proposing a normative model of expertise and an index of expertise that values both the technical and normative dimensions of good scientific discursive practice. Properly accounting for normative expertise is an essential part of living up to the covenants that make medicine, even industrialized medicine, possible. Such a model of expertise should create more room for “rank and file” members of the discourse because of their relative lack of industry relationships. We propose the index of expertise as a guide for key members of the discourse (e.g. journal editors and conference organizers) in selecting experts for peer review. The model should also be useful for those at the edges of the discourse (e.g. regulators, journalists, ethicists and critics) for seeking out the kind of expertise that best grounds the legitimacy of scientific discourse.

Works Cited

- Beauchamp, T. 1992. Ethical issues in funding and monitoring university research.” *Business & Professional Ethics Journal*, Vol. 11, No. 1 (Spring), pp. 5-16.
- Blumenthal D, Causino N, Campbell E, Louis KS. 1996. Relationships between academic institutions and industry in the life sciences—an industry survey. *New England Journal of Medicine*. 334(6):368–373.
- Campbell EG, Weissman JS, Ehringhaus S, Rao SR, Moy B, Feibelman S, Goold SD. 2007. Institutional academic-industry relationships. *Journal of the American Medical Association*. 298(15):1779–1786.
- Collins, HM. 2007. Are you fit to call yourself an expert? *New Scientist*, 15 March.
- Cuckler J. The rationale for metal-on-metal total hip arthroplasty. *Clin Orthop Relat Res* 2005;441:132-6.
- Dana, J. and G. Loewenstein. 2003. Social scientific perspective on gifts to physicians. *Journal of the American Medical Association* 290 (2): 252-255.
- Davis, Michael. 1982. Conflict of interest. *Business and Professional Ethics Journal*. 1 (4): 17-27.
- . 1993. Conflict of interest revisited again. *Business and Professional Ethics Journal* 12 (4).
- Fuller, S. 1993. *Philosophy, Rhetoric, and the End of Knowledge*, University of Wisconsin Press, 1993.
- Goldman, A. 1999. *Knowledge in a Social World*. Oxford: Oxford University Press.
- Habermas, J.. 1984. *The Theory of Communicative Action Volume One*. Trans. Thomas McCarthy. Boston: Beacon Press.
- . 1987. *The Theory of Communicative Action Volume Two*. Trans. Thomas McCarthy. Boston: Beacon Press.
- . 2000 *On the pragmatics of communication*, ed. Meave Cooke. Cambridge, Mass.: MIT Press.
- IOM (Institute of Medicine). 2009. *Conflict of interest in medical research, education, and practice*. Washington, DC: The National Academies Press.

- Jacobs J. Commentary on an article by Stephen S. Tower, MD: "Arthroprosthetic cobaltism: neurological and cardiac manifestations in two patients with metal-on-metal arthroplasty. a case report". *J Bone Joint Surg Am* 2010;92:e35.
- Rizzetti MC, Liberini P, Zarattini G, et al. 2009. Loss of sight and sound. Could it be the hip? *Lancet* ;373:1052.
- Read JL, Campbell PM. Health care innovation: a progress report. *Health Affairs*. 1988;7(3):174–185.
- Read JL, Lee KB Jr. Health care innovation: progress report and focus on biotechnology. *Health Affairs*. 1994;13(3):215–225.
- Schacht WH. The Bayh-Dole Act: Selected Issues in Patent Policy and the Commercialization of Technology. Washington, DC: Congressional Research Service; 2008. [last accessed May 20, 2013]. http://assets.opencrs.com/rpts/RL32076_20080403.pdf.
- Steens W, von Foerster G, Katzer A. 2006. Severe cobalt poisoning with loss of sight after ceramic-metal pairing in a hip--a case report. *Acta Orthop* 77:830-2.
- Tower S. 2010. Arthroprosthetic cobaltism: neurological and cardiac manifestations in two patients with metal-on-metal arthroplasty: a case report. *American Journal of Bone Joint Surgery*. 92:2847-51.
- Van Der Straeten C, Van Quickenborne D, DeSmet K. Hearing loss in a bilateral hip resurfacing. *Tijdschr voor Geneeskunde* 2012;68.
- Weber, M. 1905/1992. *The Protestant Ethic and the Spirit of Capitalism*, T. Parsons (trans.), A. Giddens (intro), London: Routledge.