*The British Journal of Sociology 2012 Volume 63 Issue 3*

# The logic of strategic ignorance[1]

Linsey McGoey

**Abstract**

Ignorance and knowledge are often thought of as opposite phenomena. Knowledge is seen as a source of power, and ignorance as a barrier to consolidating authority in political and corporate arenas. This article disputes this, exploring the ways that ignorance serves as a productive asset, helping individuals and institutions to command resources, deny liability in the aftermath of crises, and to assert expertise in the face of unpredictable outcomes. Through a focus on the Food and Drug Administration's licensing of Ketek, an antibiotic drug manufactured by Sanofi-Aventis and linked to liver failure, I suggest that in drug regulation, different actors, from physicians to regulators to manufacturers, often battle over who can attest to the *least* knowledge of the efficacy and safety of different drugs – a finding that raises new insights about the value of ignorance as an organizational resource.

**Keywords:** Sociology of ignorance; knowledge alibis; regulatory failure; pharmaceuticals; power

## Introduction

In October 2010, Jérôme Kerviel, a former Société Générale trader, was sentenced to five years in prison for breach of trust, forgery, and unauthorized computer use. Two years earlier, he had carried out a series of trades resulting in losses of nearly $7 billion for his employers. Since news of his actions first broke, the line from senior staff at Société Générale has stayed the same: Kerviel was working without the authorization of his superiors; they had no knowledge of his behaviour. Kerviel disputed this, insisting his managers persistently turned a blind eye to his actions as long as he continued to turn a profit.

The effort among senior management to demonstrate non-knowledge of Kerviel's actions suggests that the most important managerial resource during

McGoey (Department of Sociology, University of Essex) (Corresponding author email: lmcgoey@essex.ac.uk)
 ISSN 0007-1315 print/1468-4446 online.
Published by Blackwell Publishing Ltd, 9600 Garsington Road, Oxford OX4 2DQ, UK and 350 Main Street, Malden, MA 02148, USA on behalf of the LSE. DOI: 10.1111/j.1468-4446.2012.01424.x

the scandal was not the need to demonstrate prescient foresight, or the early detection of potential catastrophes. What mattered most was the ability to insist such detection was impossible. For senior staff at SocGen, the most useful tool was the ability to profess ignorance of things it was not in their interest to acknowledge. Executives harnessed the uncertainty surrounding Kerviel's risk-taking in order to absolve liability for the failures they presided over.

A similar pattern can be seen in the collapse of the UK's Barings investment bank in the 1980s. The former derivatives trader Nick Leeson was just 27 years old when he conducted a series of trades that resulted in losses of £860 million for Barings, including the loss of £143 million in a single day, a catastrophe that helped bankrupt the firm. 'In a sense', sociologists Bridget Hutter and Michael Power write, 'the Barings Bank organization had all the information which might have alerted it to Leeson's unauthorized trading. Rather than act on this information, they appear to have dismissed it as a result of 'senior management preferences for optimistic, rather than pessimistic, interpretations' of Barings' economic performance in certain sectors (Hutter and Power 2005: 14; see also Stein 2000).

The actions of senior staff at Barings and SocGen are reminiscent of Michael Taussig's assertion that 'knowing what not to know' is one of the most indispensable forms of social and political knowledge (Taussig 1999). Despite the obviousness of such a point – evoking maxims such as 'ignorance is bliss' or 'what you don't know can't hurt you' – sociologists have largely failed to treat ignorance as a social phenomenon warranting detailed empirical study. Although a handful of analyses have explored the usefulness of ignorance as a tool of governance and social control (c.f. Balmer 2012; Frickel and Vincent 2007; Gross 2007, 2010, 2012; Luhmann 1998; Merton 1987; Moore and Tumin 1949; Proctor and Schiebinger 2008; Schneider 1962; Ungar 2008), the rarity of these articles suggests, as Andrew Abbott puts it, 'a certain sociological ignorance of ignorance' (Abbott 2010: 174).

In this article, I address this dearth of attention. I examine literature that has explored the productive uses of ignorance, while reflecting on the relative paucity of such efforts. I suggest that even recent analyses focused on the problem of ignorance have tended to cement a dubious binary opposition between knowledge and ignorance. Most articles, such as Ungar's recent article on the perils of increased public ignorance, tend to view ignorance as a *de facto* negative phenomenon, something social actors have an obvious interest in seeking to overcome or to eradicate, and which sociologists have an onus to better identify so that actors are equipped to recognize and combat their own ignorance (Ungar 2008).

I argue the opposite. Through a focus on a recent controversy over the licensing of Ketek, an antibiotic drug linked to kidney failure, I explore how actors seek to preserve ignorance rather than to dispel it. I argue that in the

 

case of drug regulation, different actors often battle over who can prove to have the *least* knowledge of the efficacy and safety of different drugs, something that raises new insights about the value of ignorance in organizations.

At various stages of the testing and licensing of Ketek, different parties 1) employed risk-detection systems that seemed to obfuscate the very warning signs manufacturers were ostensibly seeking to detect; 2) selectively disclosed data in ways that increased the knowledge of some while compounding the ignorance of others; 3) directed regulatory staff to remain silent about concerns over drug safety; and 4) ignored the implications of known limitations to methodologies for detecting drug risks.

Individually, such practices cover well-examined terrain: deliberate concealment; institutional suppression of dissent; blinkered trust in risk-detection systems. Collectively, they suggest a phenomenon strangely sidelined in sociological thought: the ways that cultivating ignorance is often more advantageous, both institutionally and personally, than cultivating knowledge. I term such practices of obfuscation and deliberate insulation from unsettling information 'strategic ignorance', the mobilization of the unknowns in a situation in order to command resources, deny liability in the aftermath of disaster, and to assert expert control in the face of both foreseeable unpredictable outcomes.[2]

The first use above – the value of ignorance in procuring more resources – is perhaps the most studied to date. Particularly since Popper's insistence that science is strengthened by the admission of error, that science must prove its own fallibility in order to distinguish itself from pseudo-science, there has been increased recognition, even celebration, of the ways that ignorance and uncertainty are integral to scientific discovery. As Smithson points out, ignorance can serve as a prerequisite to learning or discovery; can help create a climate of creativity and entrepreneurship; can be harnessed to enhance the generalizability of findings or attain consensus; and can strengthen one's reputation for scientific cautiousness (McGoey 2012; Popper 1977; Smithson 1993).

Proctor has explored some of the unintended effects of the growing acceptance of the uncertainty of science, examining how industries appear to be increasingly seeking to profit from uncertain evidence – what Donald Rumsfeld famously labeled 'known unknowns' – over a product's adverse effects. Proctor suggests the tobacco industry, for example, adopted a two-fold defence when first faced with charges of tobacco's health risks.

First, a 'no proof' defence, where manufacturers, in tactics reminiscent of today's climate change skeptics, continually stressed that much scientific uncertainty shrouded claims of a causal link to cancer. 'The idea of "no proof," ' Proctor writes, 'becomes one of the two main pillars of the industry's defense against lawsuits; the other being *common knowledge*: everyone has always known about the dangers, so smokers have only themselves to blame for whatever illnesses they may contract' (Proctor and Schiebinger 2008: 13).

 

Proctor's point leads to an under-analysed aspect of ignorance: its usefulness in maintaining expert control and expanding expert jurisdiction. It has long been pointed out that a command of rarefied or exclusive knowledge is central to the definition and the maintenance of expertise.[3] What is less studied is how expert knowledge is also, to a lesser but still crucial degree, dependant on the reluctance or inability to specify the empirical value of knowledge in practice. Abstract knowledge is fundamental to a profession's ability to first, maintain autonomy, and second, to foster and enable professional expansion – the ability to apply occupational expertise beyond immediate remits (Abbott 1988).

In order to move swiftly and flexibly to new areas, such knowledge often requires a certain elasticity, and, as part of that elasticity, a *lack* of knowledge of its limits in practice.[4] Expert status is often dependent on maintaining a monopoly over what remains difficult or impossible to know empirically. I suggest that 'knowing what not to know', in Taussig's sense, is fundamental to professional jurisdiction in Abbott's sense. Previous work on ignorance has yet to consider the ramifications of this point. Sociologists have underestimated the extent to which strategic ignorance is fundamental to expert control and disciplinary expansion.

To address this dearth of attention, I make two new claims.

First, I suggest that claims of authority are often contingent what I term 'knowledge alibis' – the ability to mobilize expert ignorance in order to testify to an actor's professional credibility. Second, I argue that we need more attention to the importance of the scale of ignorance. Ignorance, I suggest, is often more valuable to institutions and institutions the more pervasive it becomes.

Below, I explore these claims further. Firstly, I review literature on the uses of ignorance. Secondly, I turn to an analysis of the controversy over Ketek in order to explore the uses of ignorance in practice. Methodologically, my analysis draws on 23 in-depth interviews with current and former employees and expert advisors at bodies such as the US Food Drug Administration (FDA), the US Congress, the UK Medicines and Healthcare Products Regulatory Agency (MHRA), and the UK National Institute for Health and Clinical Excellence (NICE), as part of an ongoing study of the ramifications of recent controversies over the safety of two classes of pharmaceuticals: SSRI antidepressants such as Prozac, and antibiotic drugs such as Ketek.

Fifteen of these interviews were carried out over 2005 and 2006, in the UK. Eight further in-depth interviews were carried out in person and by phone with FDA regulators and US policymakers in October and November 2009, including David Ross, a former FDA official featured in the discussion below, and David Graham, a current FDA drug safety officer well-known for calling public attention to the risks of Vioxx, a painkiller removed from global markets in 2004.

 

## Ignorance in the social sciences

In many ways, ignorance has been a central, though under-emphasized, focus of social scientists who have explored the uses of selective knowledge in justifying decisions in social life. Mary Douglas' work on 'structural amnesia' has long pointed out that 'certain things always need to be forgotten for any cognitive system to work' (Douglas 1986: 76), an insight echoed by Stanley Cohen's work on 'states of denial', his term for the methods and defences individuals employ to avoid acknowledging things that feel psychologically or culturally impossible to discuss openly (Cohen 2001).

Cohen and Douglas' work illuminates how the desire not to know particular facts often stems from social taboos or disciplinary constraints that make it difficult to process unsettling knowledge, something organizational theorists such as Seibel, Weick and Vaughan have explored through work on organizational disasters, where information is discounted by individuals who have no place for the information 'within prevailing modes of understanding' (Smithson 1993: 140; see also Weick 1998; Vaughan 2005; Seibel 1996).

Indeed, many advances in the epistemology of knowledge have been predicated on the realization that, as Michael Polanyi wrote of tacit knowledge, 'we know more than we can tell' (Polanyi 2009), an insight echoed by scholars as varied as Friedrich Hayek and Pierre Bourdieu. One of Hayek's fundamental, and often curiously ignored contentions was that formal economic theory represented 'only the visible tip of the vast submerged fund of tacit knowledge, much of which is entirely beyond our powers of articulation' (see Gray 1998: 15; Hayek 1945). As John Gray argues, Hayek suspected that 'neglect of this dependency of our necessarily abstract theories on a vast range of inarticulate background knowledge has led social science astray in many fields' (Gray 1998: 15; see also Friedman 2005, 2009; Riles 2010).[5]

Bourdieu was equally interested in the importance of unarticulated knowledge, He explored the role unspoken knowledge plays in the socialization process (he stressed that social norms were inculcated at a doxic, preconscious level), and the importance of tacit knowledge in maintaining social and political hierarchies. As he suggested, 'the most successful ideological effects are the ones that have no need of words, but only of *laissez-faire* and complicitous silence' (Bourdieu 1992: 133).

Influenced in part by Bourdieu, the 1960s onward has seen the growth of sociologically subgenres such as, to name just two, the sociology of practice (c.f. Benzecry and Krause 2010; Sennett 2008), and the sociology and anthropology of memory (c.f. Mookherjee 2006; Zerubavel 2007) that have taken as a fundamental premise the idea that knowledge is striated: always partial, always selective, and always vulnerable to dismissal or manipulation according to varying personal interests and structural constraints.

 

If the importance of ignorance has only been implicitly suggested in studies of tacit knowledge, a small number of studies have explicitly taken ignorance as their focus of analysis. Anthropologists and sociologists within science and technology studies have been at the forefront of such efforts, exploring what Hess and Frickel have described as 'undone science', areas of inquiry deliberately left unfunded, ignored or sidelined because the political implications of exploring them may be dangerous or unpalatable to powerful authorities (see Frickel and Vincent 2007; Hess 2007; High et al 2012; Kleinman and Suryanarayanan 2012).

Their work complements Knorr Cetina's (1999) discussion of 'negative knowledge', something she sees not as non-knowledge, or a void of knowing, but as knowledge (whether unconscious or articulated) of the limits and the adverse repercussions of knowledge. Negative knowledge is an awareness of the things we have no incentive or interest in knowing about further. As Matthias Gross writes in a seminal article on the epistemology of ignorance, negative knowledge involves 'active consideration that to think further into a certain direction will be unimportant' (Gross 2007: 749).

The concept of negative knowledge is relevant to the study of organizations, where it has long been shown that bureaucrats often refuse more resources when such resources might force them to implement policies they sense they cannot manage effectively (see Carpenter 2010; Weick 1998). Declaring new resources unnecessary or irrelevant is fundamental to meeting targets or quotas beyond individual control. Ignorance can be the haven of personnel burdened by knowledge demands.

Writing in 1949, Moore and Tumin were the first sociologists to make a strong case for explicitly exploring the functionality of ignorance, enumerating five main functions: 1) preserving privilege; 2) reinforcing traditional values; 3) preserving fair competition (justice and equal opportunity should be blind to social or economic circumstance); 4) preserving stereotypes; and 5) incentivizing hard work (ignorance of outcomes incentivizes more energetic outputs) (Moore and Tumin 1949).[6]

The richness of their analysis failed to spur a watershed of sociological work on ignorance. Only a handful of isolated analyses have emerged since, including a sadly neglected 1962 article by Louis Schneider. Schneider suggests that ignorance is implicitly central to much social theory, including Marx's conception of commodity fetishism, which only 'makes sense' if workers are willing to ignore that commodities are inextricably linked to the social relations of their production.

Two decades after Schneider's article, Merton introduced a distinction between 'unspecified ignorance' and 'specified ignorance' – in short, the distinction between things we *don't know* we don't know, and things we *know* we don't know. As Abbott writes, although it may serve as a useful empirical characterization of much scientific practice, Merton's distinction 'presupposes

 

a directionality to knowledge' which belies the fluid way ignorance and knowledge interact, overlap and outpace each other (Abbott 2010: 187).

A second problem with Merton's distinction is that it implies a neat separation between the things we do know and the things we don't. This separation fails to consider the organizational advantages of willfully magnifying one's own ignorance in order to avoid the repercussions of troubling knowledge. It also fails to engage with the challenge of determining whether someone's ignorance is simply an unavoidable handicap, or whether it is a deliberately wielded tool. In other words, whether ignorance is strategic or not.

As this article explores, this very difficulty – the challenge of proving whether someone is actually ignorant or simply feigning ignorance – is what underpins the usefulness of ignorance as an organizational resource. As I suggest below, strategic ignorance is distinguishable from deception or the suppression of data by virtue of the fact that unsettling knowledge is thwarted from emerging in the first place, making it difficult to hold individuals legally liable for knowledge they can claim to have never possessed. Strategic ignorance helps to girder and support plausible deniability, the creation of chains of command and information trails that are informal enough to be denied if questioned directly about the existence of inconvenient facts (see Lynch and Bogen 1996).

Plausible deniability and strategic ignorance share the trait of being at their most powerful when their machinations are least in evidence, when claims of ignorance appear genuine rather than manufactured. The pyrrhic challenge for scholars of ignorance is to prove the existence of something for which the very ability to evade detection is a key criterion of success. I call this challenge pyrrhic because to prove the utility of ignorance is to demonstrate that ignorance has a material concreteness that undermines its own ontological status. Ironically, once ignorance is defined, it loses its very definition.

The difficulty of proving the strategic uses of ignorance does not dispel the importance of conceptualizing the value of unknowns within organizations. Rather, it magnifies the importance of understanding the organizational pressures that render ignorance a lucrative asset, and to develop hypotheses for why and how ignorance manifests itself in different environments.

A useful example is Heimer's discussion of the uses of ignorance in HIV/AIDs clinics so overwhelmed with the task of collecting and collating data that fully processing data could thwart efforts to treat patients expediently. Heimer suggests that the strategic deployment of ignorance encompasses two phenomena: sequestered knowledge, where inconvenient facts are rendered less visible through deliberate strategies, such as creating piles of bureaucratic paperwork that obscure rather than clarify meaning; and distributed ignorance, where individuals focus exclusively on their own work, isolating themselves from exposure to unsettling information (Heimer 2012).

 

Similar practices are visible in the Ketek case, where the very processes oriented at dispelling unknowns succeeded in fomented more of them. Close attention to the Ketek case illustrates this point.

## The Ketek case

In 2004, a family practice doctor named Anne Kirkman-Campbell was sentenced to 57 months in a federal prison for mail fraud. She was convicted for forgery involving a clinical trial commissioned to test Ketek (telithromycin), a ketolide antibiotic drug manufactured by Sanofi-Aventis (Hundley 2007).

At first glance, her imprisonment appears to be a tangible sign of the efficacy of the legal infrastructure intended to curb and penalize fraud in drug testing. It is a signal that when medical researchers commit malfeasance, they suffer repercussions: a nearly five-year sentence is not an insignificant amount of time. But behind her case lies less visible struggles over Sanofi-Aventis's efforts to license Ketek, a story of ignored warnings and professional reprimands that caused at least two FDA medical officers to leave the agency over their superior's reluctance to acknowledge concerns over Ketek's safety and efficacy.

Ketek was licensed by European Medicines Evaluation Agency in 2001, and by the FDA in 2004, after undergoing three FDA reviews. During the first review, FDA reviewers discerned a number of possible side-effects, including a possible association with liver failure. An FDA anti-infective drugs advisory committee recommended that Aventis obtain more safety evidence through a large clinical trial before the drug could be approved. The company launched Study 3014, a phase III trial involving over 24,000 patients, carried out by more than 1,800 physicians across the USA.

During phase III trials, drugs demonstrated to be tolerable (something determined in Phase I trials), and then efficacious in smaller groups of patients (determined in phase II trials), are tested in large, randomized trials which aim to prove the statistically significant benefit of a drug over a comparator, such as a placebo or a comparator drug. As has become typical practice within the global pharmaceutical industry (see Petryna 2007), the company hired a contract research organization called Pharmaceutical Product Development Inc (PPD) to carry out the clinical trial.

In 2004, the FDA was informed that data from Study 3014 had been compromised by safety violations at Kirkman-Campbell and at least 10 other research sites. Despite this knowledge, the FDA awarded a license to Ketek (Ross 2007).

Three years later, after dozens of reports of kidney failure linked to Ketek, the FDA implemented label changes for the drug, banning its use for two of its three previously approved indications (acute bacterial sinusitis and acute bacterial exacerbations of chronic bronchitis), and insisting on a black-box

 

warning for the sole remaining indication, the treatment of moderate to severe community-acquired pneumonia.

Also in 2007, the US House of Representatives' Committee on Energy and Commerce launched a series of hearings to determine whether a range of parties, from the FDA to Sanofi-Aventis, knew about the adverse risks of Ketek before the drug was licensed in 2004 and chose to ignore them.

One of the individuals called before hearings was Ann Marie Cisneros, a former research associate at PPD, the research organization hired to conduct Study 3014. Introducing herself to the committee, Cisneros stated that she had formerly serviced as medical technologist in the US Air Force, and had since worked for eight years as a clinical research associate, first at PPD, and then independently. While at PPD, she was tasked to monitor compliance at Kirkman-Campbell's site. Even before visiting Kirkman-Cambell's site, she detected a number of warning signs of possible fraud. Kirkman-Campbell, who received $400 per patient enlisted in the trial, had enrolled over 400 patients, which accounted for 1 per cent of the adult population of Gadsden, Alabama, the home of Kirkman-Campbell's practice. In comparison, another research site in Gadsden had enrolled just 12 patients.

Alarmed by the volume of participants, as well as the fact that no patients had withdrawn from the trial – something unusual for such high numbers – Cisneros began investigating patient charts and found a number of irregularities. Most of the informed consent forms looked as though they had been initialed by someone other than the patient; most forms were dated by someone other than the patient; one form had obviously been forged; most patients diagnosed with chronic bronchitis had no history of the ailment, and Kirkman-Campbell had enrolled her entire staff and most members of her family in the study.

Concerned, Cisneros emailed a summary of her findings to the head of quality assurance at PPD, copying Aventis personnel into the email. She then took part in a teleconference call between PPD and Aventis where she discussed her concerns with Kirkman-Campbell's data. She also notified Copernicus, the for-profit Institutional Review Board (IRB) which had been responsible for granting ethical approval for the study to go ahead. Cisneros never received a reply from Copernicus regarding her concerns. During a later FDA investigation, she was called twice by PPD lawyers who reminded her of a confidentially agreement she had signed, and told not to speak with the FDA without Aventis approval and PPD attorneys present.

After leaving PPD, a colleague still at PPD told Cisneros that Nadine Grethe, an Aventis project manager, had coached Kirkman-Campbell on how to explain away irregularities on the trial.[7] '[W]hat brings me here today,' she stated during testimony before Congress, 'is my disbelief at Aventis's statement that it did not suspect fraud was being committed. Mr. Chairman, I knew, PPD knew it, *Aventis* knew it'.[8]

 

Not only was Sanofi-Aventis not penalized by the court that sentenced Kirkman-Campbell, but the court declared that the drug company had been victim of her fraud. They ordered her to pay $925,000 in restitution to Sanofi-Aventis. Kirkman-Campbell appealed the restitution order, arguing that Aventis 'had been made aware of the fraud at my site by PPD. At NO TIME did they attempt to stop my participation'. Her motion was later denied (Hundley 2007).

During government hearings, a member of the subcommittee pressed Cisneros, as well as Henry Loveland, an FDA criminal investigator assigned in 2006 to investigate whether Aventis had withheld information, about what exactly they felt Aventis knew or didn't know about Kirkman-Campbell's actions. 'Do you believe Aventis intentionally ignored evidence of fraud', the representative asked, 'or is it a matter that their processes and procedures or verifying fraud were faulty and couldn't have detected it?'

Cisneros' reply was clear: 'I personally believe they ignored evidence of fraud. You had to have your head stuck in the sand to have missed this'. Loveland's response was more equivocal. In his view, the company had more than ample information that *should* have alerted them to fraud at numerous research sites. But rather than alert the FDA of concerns, Aventis they took steps which, under the guise of seeking to examine Kirkland-Campbell's practices, enabled them to *avoid* acting on the fraud:

> Mr. LOVELAND. The decision-making process that Aventis used to evaluate the warnings that Mrs. Cisneros and other PPD folks raised was illogical, ineffective . . . From start to finish, their process for analyzing information coming out of the trial was poor. When you get into a traffic accident, you call a traffic cop. These folks came in and they said, We have indicators of fraud, and they called a mathematician. A mathematician didn't know what fraud looked like, and he couldn't identify it. He looked at all the data, couldn't figure out a rule to apply to the data set, came back and said, I don't see fraud. They took that to convince themselves that two of the most serious allegations raised by Mrs. Cisneros and by other PPD folks weren't indicators of fraud.[9]

Aventis's oversight system effectively made it *more* difficult, and not less, to determine whether the company's failure to act on Kirkman-Campbell's actions was itself fraudulent or not. Through the guise of vigilance, Aventis managed to deflect the possibility of inconvenient findings, finding solutions to the problem of how to remain convincingly ignorant of effects widely visible to many.

I suggest that Aventis's non-detection of unsettling facts is a form of strategic ignorance in practice, the deliberate refusal to become informed of conclusive evidence that might be counterproductive to organizational or individual aims. Strategic ignorance is different from deliberate concealment

 

for it encapsulates the varied ways that individuals can seek to preclude unsettling knowledge from emerging in the first place.

In this case, Aventis employed a statistician to investigate data where signals of fraud were *least* likely to be visible. Early on during Study 3014, as Loveland states in a FDA report, Aventis and PPD 'detected protocol violations which were significant enough to potentially affect the integrity of data at a minimum of eleven sites'. Aventis then directed a statistician, William Stager, to perform an analysis of Kirkman-Campbell's lab data. In a document later provided by Aventis to the FDA on in March 2003, Stager concluded that data from Kirkman-Campbell's sites were similar to data from the next two highest enrolling sites, and thus were not suspicious.[10]

The problem, as Loveland argued, is that statistical analyses are not capable of discerning mundane discrepancies, such as 'ink irregularities', the *ad hoc* reworking of adverse effects written in different coloured ink *after* data are first recorded. Such irregularities, which act as a warning flag to regulators that adverse effects might have been manipulated or deliberately erased, are perceptible to those dealing with handwritten reports, not to statisticians working with computerized data sets. The sanitization of irregularities, the creative ways such irregularities are obscured from public view through the very act of seeking to find them, demonstrates decoupling in practice: the effort to fulfill formal institutional requirements while insulating inner practices from scrutiny (see Meyer and Rowan 1977).

Stager's expertise is noteworthy here. Despite appearing to be, in hindsight, the *least* able to discern fraud, his conclusions were privileged over PPD staff such as Cisneros. Politically, the reasons are obvious. He confirmed what Aventis wanted to hear. Epistemologically, the implications deserve more scrutiny. The value of Stager's testimony lies less in what he found – which is nothing – than in how well-placed he was to find it. Stager had access not simply to Kirkman-Campbell's data, but to multiple sites. His tools of analysis were more sophisticated than someone such as Cisneros. Once he couldn't find a problem, it became more plausible for Aventis to assert there was nothing to find.

## Knowledge alibis

Sociologists have long pointed out the dangers of ignorance, seeing it as a 'deadly social problem with potentially deadly consequences' (Ungar 2008: 301). I am not disputing this: willful ignorance in the Ketek case resulted in a number of deaths. What *is* disputable is the subsequent inference: the assumption that curbing or minimizing ignorance is a primary goal of organizations and their members. In practice, the converse is often true. Actors thrive from what I term knowledge alibis: the ability to defend one's ignorance by

 

mobilizing the ignorance of higher-placed experts. A curious feature of knowledge alibis is that experts who *should* know something are particularly useful for *not* knowing it. This is because their expertise helps to legitimate claims that a phenomenon is impossible to know, rather than simply unknowable by the unenlightened. If the experts didn't know it, nobody could.[11]

Closer attention to Aventis's decision to commission Stager's statistical analysis helps to elaborate on this point. An outstanding question is, did Aventis deliberately try to avoid unsettling information, or was Stager's misperception of Kirkman-Campbell's fraud simply a convenient finding for them? It is difficult to know. In previous controversies over drug safety, such as in the case of antidepressants, leaked memos of internal strategy have provided conclusive evidence that companies deliberately withheld unfavorable trial results from regulators (see McGoey and Jackson 2009).

In this case, Aventis's apparent vigilance in hiring Stager helped to shield the company from similar conclusive findings. Despite Cisneros's insistence that the company was complicit in Kirkman-Campbell's fraud, and Kirkman-Campbell's insistence that Aventis knew of her own actions and never once tried to halt her, their testimony is viewed as anecdotal or personally motivated and therefore more dismissible. Stager's ignorance trumps Cisneros's knowledge. Finding an expert who knew 'what not to know' was crucial to Aventis's ability to defend their own purported non-liability.

During debates over Ketek, and pharmaceutical safety in general, a common theme emerges: claimants often struggle over who can attest to the least knowledge of a drug's effects, or of irregularities carried out during its testing, and in doing so, seek to harness the ignorance of others in order to defend their own. Such struggles emerge at every stage of a drug's development and marketing, often in slightly ironic ways. The lead author, for example, of a 2003 article on the benefits of Vioxx, removed from global markets in 2004, sought to excuse himself from liability for under-reporting the risks of heart attack by pointing to the fact that the article had been ghostwritten by Merck and not by him. The published article stated that there was no significant difference between Vioxx and the control group, despite a five-fold higher rate of heart attacks on the Vioxx arm.

As Sergio Sismondo describes, the author's rationale for the underreporting was his own ignorance, stating that

> Merck designed the trial, paid for the trial, ran the trial . . . Merck came to me after the study was completed and said, 'We want your help to work on the paper.' The initial paper was written at Merck, and then it was sent to me for editing. (Quoted in Sismondo 2009: 172)

The usefulness of ignorance in drug regulation reached its pinnacle in a legal principle known as FDA preemption, incorporated into FDA policy during the administration of George W. Bush. In practice, the policy states that FDA

 

approval of a product should immunize a manufacturer from liability suits by injured patients, with the rationale being that if FDA staff were not knowledgeable of risks, and did not warn patients, companies should not be held not responsible (Annas 2009).

Consumer groups have long fought the policy, pointing out that companies have routinely withheld data from the regulator, actively fomenting FDA ignorance even as they benefited legally from it.[12] Preemption was effectively struck down last year by *Wyeth vs Levine*, a Supreme Court case where the court ruled that a drug 'manufacturer must carry responsibility for the content of its label at all times' (Annas 2009: 1207). Although the legal doctrine has suffered recently, the ethos that behind it, the assumption that, to put it crudely, 'what you don't know can't hurt you', remains a significant resource, perhaps the greatest resource, in drug licensing and regulation more generally – a rather obvious point that is only surprising for how persistently its implications are ignored.

## The mobilization of ignorance at the FDA

One of the first FDA employees to raise flags over Ketek was David Ross, then a medical officer at FDA and now National Director of Clinical Public Health for the US Department of Veterans Affairs. Ross worked at the FDA for ten years, serving in a range of positions, from primary medical reviewer of new drug applications, to a member of the senior leadership team at the FDA's Office of New Drugs. With other colleagues, Ross has called attention to three main concerns with the FDA's licensing of Ketek: the FDA's failure to disclose to an advisory committee that data from Study 3014 was suspected to be fraudulent; the reliance on noninferiority trials in licensing Ketek; and the refusal to listen to internal concerns once evidence of post-market adverse effects arose.

The first concern emerged in 2003, during the FDA's second major pre-licensing review of Ketek. At that time, a routine safety investigation first alerted to FDA to problem at Kirkman-Campbell and other research sites for Study 3014. Despite knowing that data from the study was fraudulent, the FDA presented the data to its anti-invective advisory committee without mentioning that a criminal investigation was underway. Based on results from the study, the committee voted 11–1 to recommend approval of Ketek (Ross 2007).

Ross's second major concern with Ketek was on the methods used to test its efficacy. Since the 1960s, the FDA has insisted new drugs must be tested through RCTs in order to earn licenses. For some diseases, a drug must be shown to be better than a comparator drug or a placebo in order to earn a license. For most antibiotics, the FDA has relied predominantly on 'noninferiority' trials, where a drug simply has to be shown not to be significantly *worse*

 

than an available drug (Mathews 2006). Such trials have been a boon to manufacturers seeking to market me-too drugs similar in composition to available medicines. It is a design where demonstrating efficacy is 'easy to win on', as one former FDA medical officer said to me. By the time of Ketek's approval, 68 antibiotics had been approved for indications similar to Ketek, leading some staff to worry the risks of Ketek outweighed its negligible efficacy over available treatments.

Regardless of internal concerns with Study 3014 and growing FDA worries that noninferiority trials were inappropriate tests of a new drug's benefit and risks, the FDA approved Ketek in 2004. Three years later, in a letter to the *New England Journal of Medicine*, the FDA admitted that noninferiority trials were considered 'no longer acceptable for two for the three indications for which Ketek was originally approved' (Soreth et al. 2007: 1676).

From 2004 until 2007, despite knowing that Ketek had been licensed on the basis of a trial methodology later deemed inadequate for determining drug efficacy and safety; despite growing reports of lethal side-effects, and despite persistent complaints from staff such as Ross over Ketek's safety, the FDA maintained a front of silence, cautioning staff to stay equally silent or face repercussions to their job. In 2006, a number of FDA reviewers, including Ross, were summoned to a meeting with the then FDA Commissioner Andrew von Eschenbach. During the meeting, von Eschenbach compared the FDA to a football team and told reviewers that if they publicly discussed problems with Ketek outside the agency, they would be 'traded from the team'.[13]

That same year, Rosemary Johann-Liang, a former deputy division director in the Office of Surveillance and Epidemiology, wrote an internal memo suggesting that the FDA should move to halt pediatric trials testing Ketek in children, or at least warn parents about the risks of the drug, asking 'how does one justify balancing the risk of fatal liver failure against one day less of ear pain?' Today, Johann-Liang, like Ross, has left the agency, citing her frustration with being reprimanded for raising concerns, and telling media, 'I really advocate for drug safety, and a lot of times the agency doesn't want to hear that there are problems' (see Harris 2006b; Rubin 2007).

Between 2004 and 2006, more than five million prescriptions were written for the drug in the USA. During those years, as the *New York Times* states, fourteen adult patients suffered liver failure after taking Ketek, at least four of whom died. Twenty-three others suffered serious liver injury. Each of the patients was otherwise healthy (Harris 2006a). The people prescribed Ketek were individuals such as Ramiro Obrajero Pulquero, a 26-year-old construction worker with a wife and two daughters. He went to his physician complaining of a cold, and was prescribed Ketek. Three weeks later he was dead of liver failure (Hundley 2007).

Why would the FDA ignore internal concerns over drug safety? The reasons are complex, stemming from a mixture of financial and reputational pressures.

 

Social scientists such as Daniel Carpenter have pointed out that reputational concerns may compromise the ability of regulatory to swiftly remove a drug from market even when safety concerns are evident (Abraham 1994; 1995; Abraham and Sheppard 1999; Carpenter 2010; Light 2010; McGoey 2007). When the same agency is responsible for pre-market licensing and post-market surveillance, evidence of a drug risks calls attention to the possibility of regulatory negligence in licensing a drug to begin with. When that happens, as a healthcare lobbyist once said to me, 'are you going to admit a liability? Or are you going to keep your head down. And the answer is, so far as I can see, that the regulator just keeps its head down'.[14] Carpenter's work emphasizes the same point:

> it's perhaps audacious to claim, and certainly difficult to prove, that reputational incentives weaken the [FDA] Office of New Drugs' willingness to scrutinize drugs that have already been approved. Yet characterizations to this effect have been with us for 50 years – from medical reviewer John Nestor's 1963 testimony before Congress that FDA medical reviewers were discouraged from revisiting past approval decisions, to David Graham's lament that 'the new drug reviewing division that approved the drug in the first place and that regards it as its own child, typically proves to be the single greatest obstacle to effectively dealing with serious drug safety issues. (Carpenter 2006: 404)

Another reason why senior FDA staff members tend to suppress internal concern over drug risks is the challenge of *measuring* those risks. The difficulty in measuring risks can render strategic ignorance not simply a useful tactic in jurisdictional and reputational battles, but a necessary one.

## The scale of ignorance

Since the 1940s, when the first randomized trial in medicine took place, RCTs have become the obligatory mechanism for determining the risk-benefit profile for new medicines. RCTs are seen as the 'gold standard' for determining drug safety and efficacy, valued because the uses of control groups helps to determine whether the drug itself, or an external variable – such as the specific physiology of individual patients, or environmental factors – produces the treatment's effect (see Daemmrich 2004; Epstein 1995; 2007; Greene 2007; Marks 1997; Timmermans and Berg 2003; Will 2009).[15]

In practice, a number of factors restrict the ability of most RCTs to determine a drug's clinical usefulness, such as the fact that RCTs are often tested in populations which are unlikely to receive the drug clinically, and the fact that most RCTs have too few participants to reveal adverse risks that often appear once a drug is on the market (Healy 2001; Lakoff 2007; McGoey 2010). Despite

 

widespread awareness of the limits of RCTs for determining clinical effects, the status of RCTs as the perceived gold standard has led to situations where if an adverse drug effect does not appear on a randomized trial, regulators tend to view it as less alarming or worthy of immediate action.

Regulators know most trials are too short to reveal adverse drug effects. It is a fact acknowledged by Paul Leber, a former head of the FDA neuropharmacology branch. In a 1996 memo to Robert Temple, at the FDA's Office of Drug Evaluation, Leber states that 'too few patients are exposed to a drug during commercial development to capture adverse drug induced reaction'.[16]

Partly to combat this problem, the FDA invests substantial resources in post-market epidemiological studies intended to identify adverse effects. Typically, however, staff members at the Office for New Drugs, the office responsible for drug approvals, tend to dismiss epidemiological studies as less reliable than RCTs (Carpenter 2010). When adverse effects are not detectable on randomized trials, staff feel that such risks *should* be ignored.

David Graham, an associate director at the FDA's Office of Surveillance and Epidemiology, suggested to me that many FDA staff will

> only believe – this has been said to me more than once by people from the Office of New Drugs, very high level people – they will only believe that an adverse effect is real when a controlled clinical trial has been done that shows an effect with a p value of less than 0.05.

Unless there is evidence from randomized trial that an adverse effect was caused by a drug, FDA reviewers have difficulty accepting that a drug's risks may be severe – even though staff members know that most trials are too short to reveal those very risks. Absence of RCT evidence is taken as evidence that no risks exist: even when epidemiological data indicates a drug may be killing people in the thousands. Graham suggested the FDA has developed an 'asymmetric approach to safety' where unless a drug is shown *not* to work, regulators assume it is both safe and effective: 'The drug is effective until you prove to me it's not. The drug is safe until to you prove to me it's not. It's a very warped standard, one that doesn't protect the public'.

Faith in RCTs as the gold standard of drug testing leads to a sort of institutionally sanctioned strategic ignorance of warning signs that emerge once a drug is on the market. Graham put it this way,

> people can be blinded. They can believe so strongly in a product that they explain away things. They say, oh that was observational data, or, that person shouldn't have been in the clinical trial to start with because they didn't make the entry criteria.

Such rationalizations have led to two curious paradoxes. One is that RCTs have never been more powerful in drug regulation than today, when observers

 

increasingly acknowledge their limitations in practice (McGoey 2010). A second is that those who have most vocalized concerns with RCTs have tended to face more negative professional consequences than those who deliberately ignore concerns.

Over the last decade, FDA staff have been reprimanded for raising safety concerns in the case of antidepressants drugs, Vioxx, and, most recently, Avandia, a bestselling diabetes drug found to increase the risk of heart attack by almost 50 per cent (see Bass 2008; Harris 2010; Lenzer 2004; Lenzer and Brownlee 2008; Shorter 2009). The number of FDA staff penalized for calling attention to problems with a licensed drug suggests a truism that is both obvious and yet strangely neglected. Within large organizations, individuals often have more to lose than to gain by calling attention to dysfunction within organizations which, by necessity, tend to thrive on not articulating their own weaknesses.

Those who threaten to shatter the collective denial of unsettling problems are treated as disloyal, as whistleblowers, or as von Eschenbach stated, as poor 'team players'. Strategies are swiftly invoked to silence those who dare break codes of silence. The decision to expose deliberate ignorance, to draw attention to palpable problems is, rather perversely, treated as the most inexcusable act. Exposing problems is often more personally dangerous than quietly perpetuating them.

This reality is visible in a range of organizations and professional milieus, such as the global finance sector, where, as Gillian Tett suggests, early warning signs of systemic failure that led to the system's collapse were obscured through the social silence which prevailed around the potentially catastrophic effects of derivatives (Tett 2009). It is not that problems were not visible, but that tangible problems were left unarticulated by groups whose social solidarity was dependent on the willingness to ignore information that was not personally or institutionally advantageous to discuss openly. Ignorance is most convincing when it is shared.

Two individuals who exemplify the value of ignorance during the 2008 financial collapse are Ralph Cioffi and Matthew Tannin, former Bear Stearns hedge fund managers accused in a New York court of lying to investors about the fragile state of the funds they managed, leading clients to lose $1.6 billion when the funds collapsed in the summer of 2007. As Davies and McGoey (2012) write, the prosecution's case turned on emails which, at first glance, seemed to offer irrefutable evidence that the fund managers knew their funds were spiraling downwards – and sought to hide their knowledge from clients.

After a three-week trial, the defendants were acquitted. Jurors stated that the former Bear Stearns staff may have made bad investments, but that was not a crime. 'The entire market crashed', a juror later told media. 'You can't blame that on two people' (Davies and McGoey 2012; Kouwe and Slater 2009).

 

Pointing to their own ignorance was valuable to those who had something to gain by purporting that knowledge of impended market collapse was impossible to predict.

This point both expands upon and challenges Donald MacKenzie's work on the limits of knowledge during the financial crisis. MacKenzie has demonstrated the ways that knowledge gaps and asymmetries were a key culprit of market unrest (MacKenzie 2011). While insightful, his analysis implies, misguidedly, that such information gaps were an aberration from the norm, something actors have an obvious interest in overcoming through the application or development of more knowledge.

His analysis sidesteps the question of the organizational advantages of information gaps, the ways that the harnessing evidence of one's lack of knowledge, as Cioffi and Tannin's legal team did, is a useful strategy, one rendered more convincing the greater the number of actors engaged in the same strategies of willful ignorance.[17] In the case of the recent financial crisis, the failure to act on warning signs became simultaneously more *surprising* in hindsight (as in, how could individuals miss such obvious signs?) and more *exonerating* the larger the problem became (people missed them because everyone else did). Magnifying perceptions of one's ignorance is often more useful than gaining more information of things one might be penalized for better understanding.

'It is not the quantity of ignorance that matters', suggests Abbott. 'It is rather the quality' (Abbott 2010: 188). He is correct in pointing out the multifaceted nature of ignorance. But he underestimates the importance of the scale of ignorance. As I have shown, strategic ignorance is often more institutionally advantageous the more widely it is individually mobilized. The more pervasive strategic ignorance becomes, the harder it is to challenge or to expose, whether one is deliberately restrained, as in the case of von Eschenbach's dictate not to discuss problems publically, or whether strategic ignorance stems from unconscious adherence to institutional norms, as in the case of FDA staff who have little incentive for better understanding how their methods are inadequate.

## Conclusion

Through a focus on Ketek, this article has explored the strategic uses of ignorance, the deliberate effort to preclude, obfuscate or deflect knowledge from emerging. I have suggested we need more attention to the scale of ignorance, and the ways that, contrary to popular logic, increased ignorance does not necessarily act as an impediment to the smooth functioning of different organizations. On the contrary, organizations often function more efficiently because of the shared willingness of individuals to band together in dismissing unsettling knowledge.

 

Of course, one could argue that institutions or sectors that thrive on sustained ignorance of their own inadequacies eventually suffer repercussions. The recent financial crash is a case of point. Ignorance of the risks individuals were taking eventually imperiled the financial system's stability.

Here, however, is where the value of ignorance becomes most visible. After the system stabilized, collective ignorance – believable because of its sheer magnitude – has been a useful alibi, helping to deflect accountability for those who precipitated the crash. It has proved remarkably difficult to hold particular financial actors liable for systematic risks that few have admitted to understanding or perceiving. Ignorance has a double usefulness. First, widespread social silence enabled the perpetuation of highly profitable, however ultimately destructive, activities. Second, earlier silences were exploited in order to exonerate the actions of individuals claiming risks were impossible to detect. It was logical to claim ignorance both before and after the collapse.

This relates to my overarching point, which is that we need to resist the customary assumption that knowledge is more powerful than ignorance, or that social actors have an obvious interest in expanding knowledge and eradicating ignorance. Such an assumption limits understanding of the ways that ignorance is intentionally fostered and maintained, deflecting attention from a key social knowledge – the knowledge of what individuals aspire and struggle not to know.

(Date accepted: May 2012)

## Notes

1. Many thanks to Eamonn Carrabine, Nicolas Guilhot, Peter Jacobson, Lisa Stampnitzky, Catherine Will and Scott Vrecko for comments on the article. My analysis of the Ketek case has been enhanced through discussions with members of the Pharmaceutical Dissent project, Kate Weiner, Sujatha Raman, and Catherine Will, as well as research assistance on Ketek from Shadreck Mwale. This article was written through the support of a James Martin fellowship in science and technology studies at the University of Oxford, as well as a visiting fellowship at the Brocher Foundation, Geneva. Thanks to the Oxford STS group, past and present, in particular Noortje Marres and Tanja Schneider.

2. I first use the term strategic ignorance in McGoey 2007. Allison Bailey (2007) has separately used the term to discuss similar phenomena: the ways that ignorance is strategically maintained to serve various social and political objectives. Recently, Carol Heimer (2012) has built on the notion.

3. See, for example, work by Eyal and Buchholz (2010) for a recent discussion of sociologies of expertise in a range of fields, from science and technology studies of 'boundary work', to governmentality perspectives on the links between knowledge and power, to work on epistemic communities within international relations. All have as a starting point the equivalence of expertise with exclusivity. Far less explored are the ways that experts seek to preserve their own ignorance – perhaps as aggressively as they struggle to gain new knowledge.

 

4. See Guilhot 2011 for a discussion of how a discipline or profession's authority can be augmented and expanded to other arenas – in Guilhot's analysis, the expansion of game theory beyond economics –through de-formalizing its underlying theory. In other words, through a refusal to adhere to, or to propagate, concrete or narrow axioms, tenets or formula, disciplinary knowledge is rendered more marketable to different spheres. The inability or reluctance to know or to test a proposition empirically becomes a key professional asset – whether that advantage is kindled consciously or not. This resonates with Abbott's perception of how 'in a peculiar way, relatively less organized professions have distinct advantages in workplace competition. Because they lack a clear focus and perhaps a clearly established cognitive structure, they are free to move to available tasks' (see Abbott 1988: 83).

5. Work by Nassim Nicholas Taleb (2004) helps underscore the gravity of the failure of many economists to appreciate the limits of their own knowledge.

6. Earlier sociological work on secrecy serves an obvious precursor to current work on ignorance. Simmel, for example, was fascinated by human interest and reliance on secrecy and the 'unknown', something he deemed 'the typical error according to which everything mysterious is something important and essential'(Simmel 1964: 333).

7. By law, IRBs must oversee clinical trial research in the USA, ensuring investigators adhere to good clinical practice, such as obtaining informed consent from participants. Copernicus' apparent neglect of safety concerns raises the wider question of whether for-profit IRBs, which have become increasingly prevalent in the USA over recent years, are more lax in general in vetting trial protocols than their non-profit equivalent. See Emanuel et al. 2006 and Fisher 2009.

8. Testimony of Ann Marie Cisneros before the Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce. Feb 12, 2008, pg 15. US http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110_house_hearingsanddocid=f:48587.pdf

9. See the testimony of Henry Loveland, US Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce. Feb 12, 2008, pg 19. US http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110_house_hearingsanddocid=f:48587.pdf

10. Loveland's FDA report is available here: http://archives.energycommerce.house.gov/Investigations/KetekExhibitBinder/10001.PDF

11. The exonerating value of ignorance is not limited to pharmaceutical controversies. Numerous political catastrophes have been mitigated or justified through official insistences of ignorance. Power's work (2001) on the 1994 genocide in Sudan is exemplary on this point.

12. For cases where manufacturers have withheld data from regulators, see Abraham and Sheppard 1999 and McGoey and Jackson 2009.

13. The meeting with von Eschenbach is described by Ross during his testimony before the subcommittee hearing into Ketek. When he was later called before the subcommittee himself, von Eschenbach said that he had been trying to impress on staff that FDA was a place where, much like a pre-game locker room, 'completely different perspectives on an issue or problem can come together with mutual respect and vigorously, even aggressively, debate and discuss those issues.'

14. The source was referring to the British drug regulator's handling of SSRI antidepressants, in a case remarkably similar to the FDA's treatment of Ketek.

15. Sociologists and ethicists have paid considerable attention to detriments and advantages of the increasing use of RCTs in medicine. For enlightening discussions, see work by Timmermans and Berg and Will.

16. The quote is taken from the following AHRP presentation, available at http://www.fda.gov/downloads/Drugs/DrugSafety/UCM173472.pdf. I submitted a Freedom of Information (FOI) request to the FDA for a

 

copy of the memo, and was informed by the FDA that a search of Temple's files found no such memo. Later on, the Alliance for Human Research Protection, a NGO based in the USA, sent me a copy of the memo.

17. One exception is MacKenzie's brief mention of Goldman Sachs' remarkable proficiency at escaping virtually financially unscathed from the crisis, a feat he suggests might be attributable to the deliberate harnessing of Bourdieussian 'complicitous silence' in the face of warning signs. He then largely dismisses the import of his own assertion, noting that efforts to prove his point are hampered by the problem of access. I suggest we need more attention to the ways that firms thrive from the very strategies – complicitous silence; strategic ignorance – that sociologists often ignore because intentionality is hard to document. Otherwise, we become guilty of the very problems facing FDA staff: equating absence of evidence with evidence of absence.

## Bibliography

**Abbott, A.** 1988 *The System of Professions: Essay on the Division of Expert Labour*, Chicago: University of Chicago Press.

**Abbott, A.** 2010 'Varieties of Ignorance', *American Sociologist* 41: 174–89.

**Abraham, J.** 1994 'Distributing the Benefit of the Doubt: Scientists, Regulators and Drug Safety', *Science, Technology and Human Values* 19: 493–522.

**Abraham, J.** 1995 *Science, Politics and the Pharmaceutical Industry*, London: University College London Press.

**Abraham, J. and Sheppard, J.** 1999 'Complacent and Conflicting Scientific Expertise in British and American Drug Regulation: Clinical Risk Assessment of Triazolam', *Social Studies of Science* 29: 803–43.

**Annas, G.** 2009 'Good Law from Tragic Facts: Congress, the FDA, and Preemption', *New England Journal of Medicine* 361: 1206–11.

**Balmer, B.** 2012 *Secrecy and Science: A Historical Sociology of Biological and Chemical Warfare*, Farnham: Ashgate.

**Bailey, A.** 2007 'Strategic Ignorance' in S. Sullivan and N. Tuana *Race and Epistemologies of Ignorance*, Albany, NY: SUNY Press.

**Bass, A.** 2008 *Side Effects: A Prosecutor, A Whistleblower and Bestselling Antidepressant on Trial*, Chapel Hill, Algonquin Books.

**Benzecry, C. and Krause, M.** 2010 'How Do They Know? Practicing Knowledge in Comparative Perspective', *Qualitative Sociology* 33(4): 414–423.

**Bourdieu, P.** 1992 *The Logic of Practice*, Standord: Stanford University Press.

**Carpenter, D.** 2006 'Reputation, Gatekeeping and the Politics of Post-marketing Drug Regulation', *Virtual Mentor: Ethics Journal of the American Medical Association* (8): 403–6.

**Carpenter, D.** 2010 *Reputation and Power: Organizational Image and Reputation at the FDA*, Princeton: Princeton University Press.

**Cohen, S.** 2001 *States of Denial: Knowing About Atrocities and Suffering*, London: Polity.

**Daemmrich, A.** 2004 *Pharmacopolitics: Drug Regulation in the United States and Germany*, Chapel Hill: University of North Carolina Press.

**Davies, W. and McGoey, L.** 2012 'Rationalities of Ignorance: On Financial Crisis and the Ambivalence of Neo-liberal Epistemology', *Economy and Society* 41(1): 64–83.

**Douglas, M.** 1986 *How Institutions Think*, Syracuse, NY: Syracuse University Press

**Emanuel, E., Lemmens, T. and Elliot, C.** 2006 'Should Society Allow Research Ethics Boards to be Run as For-Profit Entreprises?', *PLoS Medicine* 3: 941–3.

**Epstein, S.** 1995 'The Construction of Lay Expertise: Aids Activism and the Forging of Credibility in the Reform of Clinical Trials', *Science, Technology and Human Values* 20: 408–37.

 

**Epstein, S.** 2007 *Inclusion: The Politics of Difference in Medicine*, Chicago: University of Chicago Press.

**Eyal, G. and Buchholz, L.** 2010 'From the Sociology of Intellectuals to the Sociology of Interventions', *Annual Review of Sociology* (36): 117–37.

**Fisher, J.** 2009 *Medical Research for Hire: The Political Economy of Pharmaceutical Clinical Trials*, Piscataway, New Jersey: Rutgers University Press.

**Frickel, S. and Vincent, M.** 2007 'Katrina, Contamination and the Unintended Organization of Ignorance', *Technology and Society* 29: 181–8.

**Friedman, J.** 2005 'Popper, Weber and Hayek: The Epistemology and Politics of Ignorance', *Critical Review* (17): i–lviii.

**Friedman, J.** 2009 'A Crisis of Politics, Not Economics: Complexity, Ignorance, and Policy Failure', *Critical Review* (21): 127–83.

**Gray, J.** 1998 *Hayek on Liberty*, London and New York: Routledge

**Greene, J.** 2007 *Prescribing by Numbers: Drugs and the Definition of Disease*, Baltimore: John Hopkins University Press.

**Gross, M.** 2007 'The Unknown in Process: Dynamic Connections of Ignorance, Nonknowledge and Related Concepts', *Current Sociology* 55(5): 742–59.

**Gross, M.** 2010 *Ignorance and Surprise: Science, Society, and Ecological Design*, Cambridge, Massachusetts/London, England: MIT Press.

**Gross, M.** 2012 'Objective Culture' and the Development of Nonknowledge: Georg Simmel and the Reverse Side of Knowing', *Cultural Sociology*, DOI: 10.1177/1749975512445431.

**Guilhot, N.** 2011 'Cyborg Pantocrator: IR Theory from Decisionism to Rational Choice', *The Journal of the History of the Behavioral Sciences* 47(3): 279–301.

**Harris, G.** 2006a 'Approval of Antibiotic Worried Safety Officials', *New York Times* July 18 2006.

**Harris, G.** 2006b 'Halt is Urged for Trials of Antibiotic in Children', *New York Times* June 8 2006.

**Harris, G.** 2010 'Research Ties Diabetes Drug to Heart Woes', *New York Times*, February 19 2010.

**Hayek, FA.** 1945 'The Use of Knowledge in Society', *The American Economy Review* 35: 519–30.

**Healy, D.** 2001 'The Dilemma Posed by New and Fashionable Treatments, *Advances in Psychiatric Treatment* 7: 322–7.

**Heimer, C.** 2012 'Inert Facts and the Illusion of Knowledge: Strategic Uses of Ignorance in HIV Clinics', *Economy and Society* 41(1): 17–41.

**Hess, D.** 2007 *Alternative Pathways in Science and Industry: Activism, Innovation and the Environment in an Era of Globalization*, Cambridge: MIT Press.

High, C., Kelly, A. and Mair, J. (eds) *The Anthropology of Ignorance: An Ethnographic Approach*, New York and Basingstoke: Palgrave Macmillan.

**Hundley K.** 2007 'Drug's Chilling Path to Market: How a Broken FDA Approved a Cold Antibiotic Despite a Wide Trail of Alarms', *St. Petersburg Times* May 27 2007.

**Hutter, B. and Power, M.** 2005 *Organizational Encounters with Risk*, Cambridge: Cambridge University Press

**Kleinman, D. and Suryanarayanan, S.** 2012 'Dying Bees and the Social Production of Ignorance', *Science, Technology and Human Values* DOI: 10.1177/0162243912442575

**Knorr Cetina, K.** 1999 *Epistemic Cultures*, Cambridge: Harvard University Press.

**Kouwe, Z. and Slater, D.** 2009 '2 Bear Stearns Fund Leaders Are Acquitted', *New York Times* November 10 2009.

**Lakoff, A.** 2007 'The Right Patients for the Drug: Managing the Placebo Effect', *Biosocieties* 2(1): 57–73.

**Lenzer, J.** 2004 'Secret US report Surfaces on Antidepressants in Children', *British Medical Journal* 329: 307.

**Lenzer, J. and Brownlee, S.** 2008 'An Untold Story?' *British Medical Journal* 336: 532–4.

**Light, D.** (ed.) 2010 *The Risks of Prescription Drugs*, New York: Columbia University Press.

 

**Luhmann, N.** 1998 *Observations on Modernity*, Stanford: Stanford University Press.

**Lynch, M. and Bogen, D.** 1996 *The Spectacle of History: Speech, Text and Memory at the Iran-Contra Hearings*, Durham, NC: Duke University Press.

**MacKenzie, D.** 2011 'The Credit Crisis as a Problem in the Sociology of Knowledge', *American Journal of Sociology* 116: 1778–841.

**Marks, H.M.** 1997 *The Progress of Experiment*, Cambridge: Cambridge University Press.

**Mathews, A.W.** 2006 'Ketek Sparks Calls to Stiffen Antibiotic Trials', *Wall Street Journal* June 13.

**McGoey, L.** 2007 'On the Will to Ignorance in Bureaucracy', *Economy and Society* 36: 212–35.

**McGoey, L.** 2010 'Profitable Failure: Antidepressant Drugs and the Triumph of Flawed Experiments', *History of the Human Sciences* (23): 58–78.

**McGoey, L.** 2012 'Strategic Unknowns: Towards a Sociology of Ignorance', *Economy and Society* 41 (1): 1–16.

**McGoey, L. and Jackson, E.** 2009 'Seroxat and the Suppression of Trial Data: Regulatory Failure and the Uses of Legal Ambiguity', *Journal of Medical Ethics* 36: 107–12.

**Merton, R.K.** 1987 'Three Fragments from a Sociologist's Notebook: establishing the Phenomenon, Specified Ignorance, and Strategic Materials', *Annual Review of Sociology* 13: 1–28.

**Meyer, J.W. and Rowan, B.** 1977 'Institutionalized Organizations: Formal Structure as Myth and Ceremony', *American Journal of Sociology* 83: 340–63.

**Mookherjee, N.** 2006 ' "Remembering to Forget': Public Secrecy and Memory of Sexual Violence in the Bangladesh War of 1971', *Journal of the Royal Anthropological Institute* 12: 433–50.

**Moore, W.E. and Tumin, M.M.** 1949 'Some Social Functions of Ignorance', *American Sociological Review* 14: 787–95.

**Petryna, A.** 2007 'Clinical Trials Offshored: On Private Sector Science and Public Health', *BioSocieties* 2(1): 21–41

**Polanyi, M.** 2009 *The Tacit Dimension*, Chicago: Chicago University Press.

**Popper, K.** 1977 *The Logic of Scientific Discovery*. London: Routledge Classics.

**Power, S.** 2001 'Bystanders to Genocide', *The Atlantic Monthly* September 2001.

**Proctor, R. and Schiebinger, L.** 2008 *Agnotology: The Making and Unmaking of Ignorance*, Stanford: Stanford University Press

**Riles, A.** 2010 *Collateral Knowledge: Legal Reasoning in Global Financial Markets*, Chicago: University of Chicago Press

**Ross, D.** 2007 'The FDA and the Case of Ketek', *New England Journal of Medicine* 356: 1601–4.

**Rubin, R.** 2007 'FDA Scientist Says She was Reprimanded for Warning', *USA Today*, December 6 2007.

**Schneider, L.** 1962 'The Role of the Category of Ignorance in Sociological Theory', *American Sociological Review* 27: 492–508.

**Sennett, R.** 2008 *The Craftsman*, New Haven: Yale University Press.

**Seibel, W.** 1996 'Successful Failure: An Alternative View on Organizational Coping', *American Behavioural Scientist* (39): 1011–24.

**Shorter, E.** 2009 *Before Prozac: The Troubled History of Mood Disorders in Psychiatry*, Oxford: Oxford University Press.

**Simmel, G.** 1964. *The Sociology of Georg Simmel*, edited by K. Wolff, New York: Free Press.

**Sismondo, S.** 2009 'Ghosts in the Machine: Publication Planning in the Medical Sciences', *Social Studies of Science* 39: 171–98.

**Smithson, M.** 1993 'Ignorance and Science: Dilemmas, Perspectives and Prospects', *Knowledge: An Interdisciplinary Social Science Journal* 15: 133–56.

**Soreth, J., Cox, E., Kweder, S., Jenkins, J. and Galson, S.** 2007 'Ketek – The FDA Perspective (correspondence)', *New England Journal of Medicine* 356: 1675–6.

**Stein, M.** 2000 'The Risk Taker as Shadow: A Psychoanalytic View of the Collapse of Barings Bank', *Journal of Management Studies* 37: 1215–29.

 

**Taleb, N.N.** 2004 *Fooled by Randomness: The Hidden Role of Chance in Life and in the Markets*, London: Penguin.

**Taussig, M.** 1999 *Defacement: Public Secrecy and the Labor of the Negative*, Stanford: Stanford University Press.

**Tett, G.** 2009 *Fool's Gold: How Unrestrained Greed Corrupted a Dream, Shattered Global Markets and Unleashed a Catastrophe*, London: Little, Brown.

**Timmermans, S. and Berg, M.** 2003 *The Gold Standard: The Challenge of Evidence-Based Medicine and Standardization in Health Care*, Philadelphia: Temple University Press

**Ungar, S.** 2008 'Ignorance as an Underidentified Social Problem', *British Journal of Sociology* 59: 301–26.

**Vaughan, D.** 2005 'Organizational Rituals of Risk and Error' in B. Hutter and M. Power (eds) *Organizational Encounters with Risk*, Cambridge: Cambridge University Press.

**Weick, K.** 1998 'Foresights of Failure: An Appreciation of Barry Turner', *Journal of Contingencies and Crisis Management* 6: 72–5.

**Will, C.** 2009 'Identifying Effectiveness in "The Old Old": Principles and Values in the Age of Clinical Trials', *Science, Technology and Human Values* 34: 607–28.

**Zerubavel, E.** 2007 *The Elephant in the Room: Silence and Denial in Everyday Life*, Oxford: Oxford University Press.

 