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Marketing Clientelism vs Corruption

Pharmaceutical Off-label Promotion on Trial

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In 2011, in the midst of working on a project aimed at countering the unresponsiveness of industry, regulators and physicians to adverse drug events (see www.rxrisk.org), I received a phone call from a New York law firm representing those seeking damages for the sudden decline in the value of their shares in Medtronic Corporation. Medtronic, a Minneapolis-based manufacturer of medical devices ranging from mechanical heart valves and heart-lung machines to surgical supplies, produced Infuse Bone Graft (hereafter Infuse), the brand name for bone morphogenetic protein-2, or BMP-2. They had been implicated in a scam to expand the sale of that product beyond the uses approved for it by the US Food and Drug Administration (FDA).

To gain approval by the FDA, new drugs must be demonstrated as safe and effective for each of their intended uses. Intended uses are the 'indications' for which a drug is tested, and if the drug is licensed, they are described on the label. Off-label prescribing means prescribing for uses other than those approved by the FDA. Physicians are permitted to prescribe for unapproved or off-label uses but, given the commercial motivation of manufacturers to encourage ever-expanding sales of their products, it is illegal for firms to promote such use.

Following reports of injured patients, unlawful kickbacks to doctors and allegations of falsified data published in scientific journals, Medtronic's share price fell. Inquiry into the matter revealed that in 2006–07 an astounding 85 per cent of Infuse sales were for

off-label uses, a rate that experts felt could hardly be achieved without off-label promotion.

Licensed for use in 2002, Infuse had revolutionary potential for application in spinal fusion surgery. That surgery is performed to reduce back pain by eliminating or reducing friction between vertebrae, and about 450,000 spinal fusions are performed in the United States annually, despite evidence that, for most patients, physical therapy works just as well (Resnick and Bozic 2013). Surgery has conventionally entailed harvesting bone from the hip and grafting it between vertebrae in the back, a procedure that is time consuming and painful. BMP-2, the bone growth agent in Infuse, was designed to help bypass the conventional grafting procedure. Unfortunately, proteins like BMP-2 can easily stimulate dangerous bone growth outside of the fusion area.

When Infuse was licensed, the FDA limited its use to a narrow range of spinal surgeries performed under specified conditions: it could be applied only in a 'single-level infusion' in the L4-S1 region of the lumbar spine in surgery intended to remedy disc collapse; the spine could only be approached through an incision in the abdomen, rather than from the back; it had to be used in conjunction with a device called an LT-Cage. These restrictions were imposed after clinical trial data revealed frequent adverse events when Infuse was used in other ways. The causes of the adverse events remain undetermined, but their consequences could be dire because Infuse is inserted near the spinal cord.

The restrictions and precautions indicated on a drug's label, if heeded, clearly limit its market potential. It may be difficult to estimate what the sales potential of Infuse might have been without off-label promotion, but assuredly it was only a small fraction of the $800 million reported for several years in the mid-2000s.

In June 2011, in an unprecedented move, *The Spine Journal* devoted an entire issue to repudiating the company-sponsored studies that had encouraged extensive off-label use of Infuse. The issue revealed that doctors who appeared to be co-authors of studies supporting off-label use of Infuse frequently had only put their names to articles written by a publication firm hired by Medtronic, and had been paid to do so. The *Spine Journal* authors linked use of the product to a number of adverse consequences: 'Uncontrolled bone formation and the need for additional surgery; life-threatening inflammation; infections; implant movement; cancer risk; and effects on nerves leading to radiating leg pain, bladder retention and a complication that causes sterility in men' (Fauber 2011). Two years later,

Annals of Internal Medicine published a comprehensive study that found no advantage from using BMP-2, and many risks (Resnick and Bozic 2013).

The New York law firm that telephoned me in 2011 was involved in what turned out to be a consolidated class-action suit against Medtronic. The complaint in that suit stated:

> Although undisclosed to investors, the first-hand accounts from over a dozen former Medtronic employees demonstrate that this extraordinarily high off-label use was driven by the Company sales force, which would direct doctors to Medtronic-compensated consultants or 'Key Opinion Leaders' in the medical field who were surgeons paid by Medtronic to promote off-label use of INFUSE Bone Graft . . . [Medtronic] materially misled investors . . . [because it did not inform them] that INFUSE Bone Graft sales were primarily dependent on higher risk off-label use of [the] product. (US District Court 2009: 3–4)

In other words, Medtronic had deployed physicians who were not formally their employees as part of their off-label promotion scheme to expand the use of the product. In language I have developed elsewhere to describe this procedure (K. Applbaum 2006a, 2009a), Medtronic had incorporated physicians into the company's distribution channel for the drug (i.e. as sales staff), even though they were not overtly part of it.

In part due to the pressure exerted by the public rebuke, and in light of Medtronic having recently been censured by the FDA for making false claims about another product (FDA 2012) in March 2012, the company agreed to settle for $85 million (I was not involved in the suit) (Stempel 2012). The company continues to deny any wrongdoing.

The situation I have described concerning Infuse points to a state of affairs in the pharmaceutical industry that helps to illuminate the concern of this volume, which is the relationship between neoliberalism, economic activities and the perspectives from which those activities are seen as deviant and perhaps wrong. One of the central elements of neoliberalism is its stress on the free market. The Infuse case indicates that in the pharmaceutical industry this stress has a corollary that is touted less widely – namely, pressure to market freely, a pressure that can lead to questionable practices. The incorporation of influential physicians, with their advocacy of off-label use of Infuse, into the marketing activities intended to increase the sale of the drug is a sign of such pressure. The result, the apparent widespread use of Infuse in ways and for conditions that the FDA

had not approved, would strike many people as the consequence of economic wrongdoing.

In this chapter I pursue the ways that pharmaceutical firms market their wares freely, not simply by catering to demand for their drugs, but by doing what they can to create that demand. I do so not only because it is revealing in its own right, but also because it helps to point to the difficulties we can confront when we try to distinguish routine practice from the deviant, the wrong and the criminal. I approach pharmaceutical marketing in terms of the difference between what I call 'marketing clientelism' and corruption.

Separating Clientelism from Corruption

The Medtronic case is but one among a spate of suits prosecuted since the early 2000s under the False Claims Act, a whistle-blower statute permitting private citizens to file suits on behalf of the federal government (see Lansdale 2006). These suits have alleged that the defendants have made false claims about drugs to promote off-label use, and have resulted in the recovery of over $15 billion from the world's most reputable drug companies (Herman 2014). Despite harsh penalties and the imposition of rigorous compliance stipulations, called 'corporate integrity agreements', which are expensive and laborious to implement, malfeasance in the industry appears to continue. A multidisciplinary subfield of the social science of medicine called critical pharmaceutical studies has emerged to report on the myriad manifestations and mechanisms of corruption in the industry, from rigging clinical trials and the ghostwriting of scientific publications to the outright purchase of influence. One of my purposes here is to consider how and why wrongdoing in the industry continues at such a pace despite the manifestly credible threats of prosecution and increased government vigilance.

In earlier research, I observed that there appears to be a misalignment, conflict and even competition between the values of medicine and public health on the one hand, and those of pharmaceutical marketing on the other.

> Medical, scientific value consists in a discovery's capacity to explain phenomena verifiably and then be applied to reduce human suffering from disease. Marketing value, by contrast, is fluid, relative, and contingent on perceived utility. Marketing value is measured in accordance with its ability to achieve product differentiation, which refers to the process of making one's product offering appear unique in the marketplace and superior to those of one's competitors. . . . Pharmaceutical value has increasingly become a marketing proposition, not a scientific one. What is valuable to marketers can be meaningless, dangerous, and costly to everyone else. (K. Applbaum 2009b: 15–16)

Among the criticisms I received for that line of thinking, one reader questioned my contrast between private (drug company) and public (medicine) spheres, pointing out that the distinction was in actuality difficult to draw because the boundary between them is porous and because in its everyday practice there is no such thing as disinterested science. The interests are not always commercial, but they are always there (Robert Rosenheck, pers. comm., 2009–10).

Without quite abandoning the original duality of brand and medical value, which echoes the familiar duality of exchange and use value, one could propose a more inclusive approach by framing the discussion in terms of the normative social exchange mechanisms by which pharmaceutical companies seek to advance their interests. One could ask under what circumstances these might be seen as working for and against the public health interest, with that interest being seen as served by drugs and devices that do more good than harm in the population, as per FDA guidelines, and that do so in keeping with legal marketing practices. If a firm's activities fail these two criteria, most people would classify them as corrupt.

However, to say of an activity that most people would see it as corrupt is not the same as saying that it is illegal. For instance, what if that activity were so widespread that the industry could not function normally without it? In such a case, the activity that most people would condemn would not be deviant, but would be the norm within the industry, and it would be difficult to challenge legally. It is this ambiguity that I will explore below in the suit against the makers of the drug Risperdal for illegally promoting it. Risperdal was developed by Janssen Pharmaceutica, a division of Johnson & Johnson. For convenience sake, in what follows I shall refer to the defendants in the suit as J&J.

The type of activity that the suit illustrates, and that is perceived as normal by industry actors, is the system of social exchange that I call marketing clientelism. I offer a hypothetical example of this sort of clientelism, though it involves the editorial rather than the marketing sort. Some years back, a colleague of mine teaching at a prestigious university was appointed editor of a well-known academic journal. Like many others, I felt that, under his direction, the quality of the journal began to improve. It also came to be remarked that a

disproportionate number of his friends and colleagues were showing up in the table of contents. Critics grumbled that the editor's apparent favouritism was a form of corruption and should be condemned. Fairness, they said, is imperative because junior faculty rely upon publications in leading journals, like the one he edited, for promotion and tenure. Others countered that the appropriate aspiration of every journal editor is to publish high-quality papers, and that the editor had mobilized his personal networks to solicit an improved pool of submissions. In my terms, this was editorial clientelism, and therefore its benefits might be tolerated or even encouraged.

The border between clientelism and corruption is fuzzy, and in academic journals efforts to police it include having editors hold the post for a limited time and having an editorial board that is strongly involved with editorial decisions. There is, however, no absolute solution to the problem of the messy overlap of the two. (In the end, people in my ken concluded that the only accusation that could properly be laid against the editor was that he was too obvious in his partialities.)

Among the academic disciplines, political scientists and development theorists often seem to see little difference between the two. They regard clientelism as a near synonym for corruption, in which formal institutional rules are bypassed in favour of a resort to 'personal, particularistic ties to obtain preferential access to goods and services' (Torsello 2012: 271). It is suggested that this is more observable in non-Western societies, either because corruption is held to be concomitant with 'poverty, ignorance, repression of women, fundamentalism, fanaticism and irrationality' or, conversely, because clientelism 'has a positive function in development because it "fills the gap" left by partial bureaucratization and the incomplete penetration by the state' (Halle and Shore 2005: 3).

On the other hand, sociologists and anthropologists have been more prone to treat clientelism as a thing on its own, rather than as a cousin of corruption. So, they have looked for characteristic features of clientelism, including dyadism, unequal power relations or verticality among transactors, informalism and conditions of scarcity (Scott 1972; Gellner 1977; Eisenstadt and Roniger 1984). A similar approach has been taken by many seeking to understand marketization in places like China, with scholars linking clientelism with markers of stability in investment, information flows, social trust and other lubricants of market transaction (Wank 1996).

In this chapter, I straddle these different approaches. Marketing clientelism may, as I show, be associated with corruption. However,

I also want to emphasize its ***strategic*** use by corporations to further their goal of having stable distribution channels for the sale of their products (K. Applbaum 2009b). There is also a more specific reason to stress the difference between clientelism and corruption. The case that I describe centres on a court proceeding, where an absolute rather than relative judgement had to be made as to whether the company in question was guilty of off-label promotion (corruption) or rather was engaged in just the normal dissemination of information about their product through expert channels (marketing clientelism).

That case was brought by Texas Medicaid, the state health insurer, against J&J over the marketing of the antipsychotic drug Risperdal. I had the opportunity to attend the trial in its entirety in January 2012, in Austin, Texas. All quotes in the text concerning the trial are taken from my notes.

Case Study in Real Time: Risperdal on Trial in Texas

Between 2009 and 2011, Johnson & Johnson and Janssen were sued successfully for fraudulent marketing practices. They had to pay $257.7 million in Louisiana, $327 million in South Carolina and $1.1 billion in Arkansas (an additional $2.2 billion was levied in criminal and civil fines in 2013) (Herman 2014). On 10 January 2012, Texas launched its suit against J&J, claiming that the company defrauded the state of $579 million.

The case involved the marketing of 'atypical' or second-generation antipsychotic (SGA) medicines, of which Risperdal is one. As I explain below, these were introduced in the 1990s and were said to be better than the older, first generation antipsychotic medicines (FGAs), which appeared in the 1950s. There is no easy synopsis of the combined commercial and medical history of this class of drugs, but as will become clear, it is reasonable to conclude that their success lies far more in the commercial than the medical realm. Apart from the body of medical research now testifying to this, common sense resists the idea that antipsychotic drugs merited becoming the best-selling class of pharmaceuticals in America. In 2010, a small number of SGAs (including principally Risperdal, Zyprexa, Seroquel, Abilify and Geodon) had sales of $14.6 billion in the United States alone; to put that in perspective, it is equivalent to 1.5 times the public expenditure for all healthcare in India.

Risperdal earned J&J $34 billion during its 17-year patent period. Those with no first-hand knowledge of how large corporations work

cannot easily comprehend the size and complexity of the machinery necessary to generate revenues on that scale. Explaining this to a jury was the challenge facing the Texas Attorney General's office, which had gathered a massive amount of information but had only a handful of hours to make their case.

In the plaintiff's opening statement, their attorney, Tom Melsheimer, accused J&J of implementing a 'systematic scheme . . . not a one-time event, not an accident'. The purpose of that scheme was to turn a drug designated for narrow use in the treatment of schizophrenia into a $34 billion pill with a 97 per cent profit margin, thereby defrauding Texas taxpayers of $579 million.

How could the company have accomplished this feat? Melsheimer alleged that the company did so in four ways: they influenced usage guidelines by bribing Texas officials; they illegally promoted the drug for use in children (half the patient population for the drug is under the age of thirteen); they made false claims that Risperdal is safer than other antipsychotic drugs; they confabulated research to support the claim that it was cost-effective to the taxpayer, even though it cost forty-five times as much as generic competitors and was not shown to be superior to them. All of these were, or were facilitated by means of, off-label marketing.

Melsheimer referred to warning letters sent by the FDA challenging the company's marketing copy, which had claimed that its drug was superior in efficacy and safety to FGAs. He argued that the company 'seeded' the scientific literature with ghostwritten articles claiming the drug's superiority. Finally, he alleged that bribes, in the form of 'unrestricted educational grants' and honoraria, were given to Texas medical officials serving on the influential Texas Medicines Algorithm Project (TMAP).

TMAP was set up in 1994, one year after Risperdal was launched in the United States. Initially it was funded by J&J, but soon thereafter all of the other major pharmaceutical companies had signed on as well. TMAP started with a panel of experts convened to produce a consensus on the use of antipsychotics. The first set of TMAP guidelines concluded that the SGAs, including Risperdal, were the drugs of choice for the management of schizophrenia (Healy 2006).

The defence attorney, Steve McConnico, appealed to jurors' common sense, their trust in doctors' judgement and their faith in the American free-market system. McConnico listed the debilitating side effects of FGAs, arguing that Risperdal does not cause them: you 'wanna talk about cost effectiveness? Knock down some of these [side effects]'. He said that FGAs address only the positive symptoms

of schizophrenia (psychosis, delusion, hearing voices), but Risperdal also helps with the negative symptoms (inexpressiveness, lack of interest in life, monosyllabic speech), and so makes it easier for people to go back to work and lead normal lives (see K. Applbaum 2006b). Independent research, including the famous CATIE study (Clinical Antipsychotic Trials of Intervention Effectiveness; see Stroup and Lieberman 2010) discussed below, has shown these claims to be false advertising – but that is precisely the point. The defence sought to redeploy J&J's Risperdal marketing messages that had worked so well on doctors and others, only this time on the jurors.

In contrast to the prosecution, the defence attorney delivered a folksy, down-home speech about 'the real world'.

> The idea that we're some kind of master puppeteer that can control all these doctors all over the world and the country and say you're going to give this drug is simply not common sense. . . . Their whole theory is we pulled some smoke screen off [*sic*] the whole medical community. . . . That doesn't make one bit of sense. The idea that a drug rep [i.e. representative, effectively in sales] is telling a doctor how to prescribe a drug doesn't work. These drugs are prescribed by doctors.

Finally, McConnico appealed to the jurors' presumed acceptance of the market doctrine of value and truth: 'Now, the reason Risperdal did well was because they were superior. It's that simple. The marketplace proved it'.

I have described the outlines of the position of the plaintiff and the defendant. Those positions refer to facts and to plausible inferences from them. I said that the difference between corruption and marketing clientelism is often fuzzy. Part of that fuzziness revolves around the meaning of what seems to be a fact, the measure that we should use to evaluate, and even identify, a fact. I turn to that now.

Establishing Not Just Facts, but the Measure of Facts

The first deposition presented in the trial was that of Thomas Anderson, who had been one of two managers responsible for launching Risperdal in 1993. The exhibits placed before the jury included a slide from the early planning days, entitled 'Building a Consensus'. The slide, presumably Anderson's handiwork, exhorted the marketing team to 'assemble an expert task force and body of knowledge . . . formulate guidelines: Key experts ⇒ Thought leaders ⇒ Rank and file'.

The expert task force that was assembled included three psychiatrists. One was Dr Allen Frances, Chairman of the Department of Psychiatry at Duke University and head of the group that assembled the fourth edition of the *Diagnostic and Statistical Manual for Mental Disorder* (DSM-IV). Another was Dr John P. Docherty, Professor and Vice Chairman of the Department of Psychiatry at Cornell University. The third was David A. Kahn, Associate Clinical Professor of Psychiatry at Columbia University. These men accepted a total of $942,669 from the drug company, mostly in the form of 'unrestricted educational grants' to their newly formed company, Expert Knowledge Systems (EKS), to prepare practice guidelines for the treatment of schizophrenia. The guidelines, which formed the basis for TMAP, endorsed the use of SGAs, including Risperdal, as the preferred treatment, dislodging the FGAs from that position.

The $942,669 given to the company that those three experts had formed needed to be measured in terms of the issues important in the court case. In the deposition, the attorney for the state, Tommy Jacks, asked Anderson: 'Did it ever occur to you that in authorizing substantial payments to their business, that their independence or objectivity might be compromised in any way?' No, Anderson replied. They were involved in *education*. Jacks then asked:

> When EKS said they would help you 'achieve more broad strategic objectives . . . influence state government . . . build brand loyalty and commitment with large groups of key providers around the country . . . develop pharmaco-economic studies' and be in touch with NAMI [the National Alliance for the Mentally Ill] to develop educational materials for rapid implementation of guidelines. . . . When they said, 'We want to ensure that all of Janssen's needs are addressed so that Janssen can succeed in its efforts to promote Risperdal throughout the country', are you making a distinction between promotion and education?

On the second day of the trial, Dr Alexander L. Miller was called to the stand. He was Professor of Psychiatry at the University of Texas Health Center at San Antonio and, according to the description of him on the University of Texas website, Director of the Schizophrenia Module of TMAP. Miller confirmed that J&J provided some of the funding for TMAP, but took umbrage at the suggestion that the consulting money he accepted from J&J, more than $70,000, might have affected his objectivity when he offered recommendations regarding the guidelines, which ultimately designated SGAs, including Risperdal, as the preferred treatment for schizophrenia.

The prosecutor challenged Miller's integrity and objectivity, and these were defended during cross-examination by the defence attorneys. They reviewed, in painstaking detail, Miller's gold-plated credentials: Yale, Washington University, the National Institute of Mental Health (NIMH), Massachusetts General Hospital, Harvard, Distinguished Life Fellow at the American Psychiatric Association and twenty years of service to the State of Texas, in addition to his full professorship at the University of Texas.

My initial assumption was that the extended review of Miller's credentials was to substantiate his credibility before the jury so that they would not think his judgement was corruptible by J&J money. I had a different thought when Miller listed among his accomplishments that he was on the advisory board of, and a Texas co-researcher for, CATIE, the selfsame drugs trial the plaintiff was using to establish that the SGAs are not superior to the FGAs. My new thought was that the defence was not seeking directly to exculpate Miller of any possible wrongdoing. Rather, Miller's positions and accomplishments were described in order to establish what it means to be trustworthy in a particular sphere of professional activity, a sphere that was central to the suit that the jury was hearing. That is, the case would turn on whether the jury would think that Miller and people like him were involved in corruption by illicitly taking money from the drug industry in return for favours, or whether they were engaged in marketing clientelism, the kind of relationship normal to the dissemination of new, vital information about medicines. If the latter, then common sense about conflicts of interest would not apply, and this was precisely what the defence was seeking to establish. As Tom Anderson, the product manager for Risperdal, had said when the prosecutor had interrogated him about giving money to key opinion leaders, funding speaker bureaus, making unrestricted grants and the like, 'I don't recall the specifics, but this is a usual and customary practice within the pharmaceutical industry'.

In other words, the defence was telling the court that, whatever may be the case elsewhere, in medicine the taking of company money while serving on guideline committees, being involved in the compilation of the DSM-IV or being a member of editorial boards is not regarded as a conflict of interest. On the contrary, it is difficult to rise to prominence in academic medicine without participating in give-and-take relationships with pharmaceutical companies. Indeed, not just academic status but the very science and policy of psychiatric medicine are co-constituted by drug companies and leading psychiatrists. Miller himself assumed this. Like a Shakespearean villain who

feels completely justified in his actions, he responded to the defence attorney's question about how this charge to his reputation made him feel: 'I think it's grossly inaccurate and unfair and – and I feel like a pawn in somebody else's game'.

Miller shared the witness stand with Dr Steven Shon, the former Medical Director for Texas Mental Health and Mental Retardation (TMHMR). The prosecution systematically exposed Shon as having violated his contract with the State of Texas. They brought as a witness a fraud investigator for the state's Medicaid division who showed, among other things, that Shon did marketing work for J&J during working hours and that he accepted moneys that would not have been offered to him had he not occupied the position he did at TMHMR, which was illegal. Like the expert task force described above, Shon had helped J&J to figure out how to make Risperdal sell so well.[1]

Other individuals, including Dr John Rush, Dr Lynn Crismon and Dr John Chiles, were also identified as having received money from J&J while serving on the TMAP panel. The Texas director for NAMI, Joe Lovelace, also took money from J&J, some of which was deposited in an account under the name of his wife's law firm. J&J referred to these relationships as 'strategic alliances', a term borrowed from the management literature, where it refers to a relationship between two companies, often competitors to each other, that seek to cut costs or expand capabilities by joining forces (K. Applbaum 1999).

For a researcher like myself interested in the rationality (and irrationality) of medication prescription practices in psychiatry, the first point brought out in the cross-examination of Steven Shon struck a chord. Shon said that the reason TMAP came about was because prescription practices across the state were erratic. He said that if a person visited six psychiatrists, he might receive the same diagnosis from all six but could still be prescribed different medications by each one.

The revolutionary DSM-III was constructed, among other reasons, to standardize diagnostic criteria (Kleinman 1988). Why should there not be another undertaking, such as TMAP, to standardize treatment programmes? The failure of this logic does not lie in the aspiration to rationalize treatment, but in the current scientific limits of psychopharmacology, particularly in the non-specificity of the drugs and the variability of patient response, beneficial or adverse, to different drugs. The effort to establish a fairly strict algorithm (the 'A' in TMAP) for treatment in psychiatry is to impose pharmacological progress where it has not yet been achieved.

For J&J and the other firms that sold SGAs, the key implicit messages they wished to convey about their drugs were that this progress had in fact been achieved and that psychiatrists should espouse treatment standardization. In their optimism, many psychiatric researchers may have embraced the vision of progress that the drug companies were touting with the SGAs.[2]

A Matter of Trust: Clinical Trial Evidence vs Physician Judgement

The system of influence described above is part of the operation of a reliable machine for creating blockbuster demand, as readily for unworthy as for worthy drugs. A key source of the influence wielded by pharmaceutical companies lies in the design, reporting, publication and dissemination of data from clinical trials. Those trials are used to evaluate the efficacy and safety of newly devised medicines, and to investigate new uses for existing ones. In the past few decades, the standard form has become large-scale randomized controlled trials (RCTs). These produce the large volume of data that allows statistical analysis of the results, which is taken to be the most reliable way to demonstrate true drug effects. The movement advocating RCTs is called evidence-based medicine.

Much of the Risperdal court case turned on the presentation and interpretation of clinical trial data associated with the drug. The plaintiff had already made several references to CATIE, a trial of the effectiveness of antipsychotics drugs carried out in the United States, and to CUtLASS (Cost Utility of the Latest Antipsychotic drugs in Schizophrenia Study), a similar trial carried out in the United Kingdom. The plaintiff urged the jury to regard these studies as trustworthy because they were conducted not by drug companies, as most trials are these days, but by independent researchers. Although the plaintiff lawyer did not mention it, the CATIE study cost $42 million, involved 1,493 subjects and 400 researchers from fifty-seven sites across the country and was the largest comparative-effectiveness trial in the history of the mental health field. The rationale for the study lay in the ambiguity of clinical data concerning the comparative effectiveness and side effects of four drugs (SGAs) that had been introduced in the 1990s.

Results from CATIE and CUtLASS were published in the mid-2000s, near the time when the patent for Risperdal would expire. Both trials found that Risperdal and the other SGAs were no better than the older FGAs on measures of efficacy or tolerability. Additional

studies pointed out that SGAs had a number of side effects of their own, in addition to the side effects associated with the FGAs. For most, this was an unexpected finding because prior studies of SGAs, such as the ones that supported the recommendations of TMAP, had ostensibly shown the reverse. If the scientific evidence supporting claims to SGA superiority were dubious, not to say rigged, then TMAP would look even more like a scam.

Echoing the SGA manufacturers' sustained efforts to discredit CATIE, in their opening statement counsel for the defence asserted that CATIE had many scientific failings, and they concentrated on the many published studies showing the superiority of the SGAs. As part of this, the defence put a map up on the screen showing the many places in the world where studies of Risperdal had been completed, calling it 'one of the most studied drugs in history'.

While RCT evidence would form an important part of the case, it could not, by itself, be expected to prove or disprove the defence's claim for the superiority of Risperdal as an antipsychotic agent, for several reasons. First, there is a mass of evidence, and different parts of it support different conclusions. Setting aside rigged studies, which are disseminated as marketing and therefore reach a wider audience than do independent studies, even the accuracy of conscientious research can never be fully substantiated. No clinical study is perfect, and flaws can always be identified that will encourage sceptics to deem a given conclusion invalid. There exist only a few clinical researchers fully qualified to interpret the highly specialized studies associated with antipsychotics, and those people are entrenched in disagreement with each other, sometimes made rancorous by accusations of bias. Second, use of this kind of evidence is problematic in a courtroom because conclusions reached in a court case and a clinical trial rest on different standards. Courts demand absolutes (guilty or innocent) whereas medical practitioners commonly make do with probabilities, since this is the best they have. Finally, no one can expect jurors to be able to make sense of RCT results anyway, no matter how patiently they are explained. In the end, most jurors have to decide on the basis of how well they trust the experts chosen to present scientific testimony in the courtroom.

Enter Clinical Experience

The plaintiff called to the stand Dr Jim Van Norman, a psychiatrist who completed all his training and licensing in Texas and had been practising in Travis County, where the court was located, for twenty-three years. He was director of a community mental health centre, exactly the sort of clinic that treats uninsured and Medicaid patients and that had a budget of the sort allegedly targeted by J&J through the TMAP initiative.

Van Norman said that he supervised the equivalent of fifteen full-time 'prescribers' who treat about 6,500 adults and 1,100 children per year, twice what they are budgeted to do. (In good dramatic fashion, this mention of budgetary constraint foreshadowed expressions of outrage over the alleged crime of promoting a drug that cost forty-five times as much as others that work just as well.)

The state's attorney, Tommy Jacks, asked Van Norman to think back to when Risperdal was first introduced in the 1990s: 'Do you recall any of the sales messages that you heard from Janssen representatives about their drug?' He replied:

> The biggest selling point as I recall was that . . . this medication was much more effective . . . at managing the negative symptoms . . . things like not wanting to go out and get a job or just having no enjoyment in life. . . . Risperdal was represented to me as being a safer medication than the first-generation antipsychotics, that we didn't have to worry as much about the extrapyramidal motor symptoms . . . and as an added benefit, that in the long run it was less expensive to the system because these medications were so effective, they would keep people from going into the hospital.

Jacks asked Van Norman whether TMAP affected prescription practices at his centre. 'Yes', Van Norman bluntly replied. This line of questioning was important because one of the defendant's recurrent claims was that TMAP was just a guideline and in no way constrained doctors to a particular medication choice. If TMAP was not enforced in any way, then how it was put together would be irrelevant to the allegation that the defendants had overcharged Texas by $579 million.

Van Norman explained that a physician at a clinic who chose to deviate from the TMAP recommendation, for instance by not prescribing an SGA as an initial treatment, had to document and justify that choice. Failure to do so could lead to sanctions and financial penalties. Physicians were, moreover, required to attend training programmes and quarterly meetings, in part to assure that they understood these rules.

Jacks asked Van Norman about his current use of SGAs and FGAs. Van Norman said he did sometimes prescribe SGAs, but that he uses the FGAs more frequently. He explained that he was greatly influenced by the CATIE and CUtLASS studies, which he described as unbiased by drug company funding. Jacks asked him

if he prescribes FGAs in the same manner he did in the early 1990s, before the introduction of Risperdal. This was a question calculated to bring out an important point for the plaintiff's argument – namely, the standard SGA manufacturer's argument, the one also put forward by the defendant, that FGAs cause extrapyramidal syndrome, including the dreaded tardive dyskinesia (TD), which SGAs do not. Van Norman confirmed that he did, meaning he did not believe that use of FGAs increased the risk of TD. He added that the FGAs had an additional advantage, for they do not increase the risk of diabetes in the way that SGAs do (Koller et al. 2003), and so reduce the need to pay the costs associated with monitoring patients for lipids, glucose tolerance and weight gain.

He expanded on the side effects of the SGAs in comparison with the FGAs. He and his colleagues, he said, were frequently astonished by the speed and severity of weight gain some patients experienced on SGAs, which were as much as 20–30 lbs in three months. Further, on even the smallest doses of Risperdal (1 mg), some women developed hyper-prolactinemia, causing them to lactate, a side effect that would distress someone who is not nursing.

> Jacks asked: 'And TD? Have you seen that in [patients taking] the older drugs?'
> Van Norman replied: 'Not under my care'.

It seemed to me that the cross-examining defence attorney, John McDonald, was stunned by some of Van Norman's testimony, for it was almost certainly a radical departure from the brief that J&J would have given him. Even so, McDonald stuck to his team's strategy. He tried to discredit the witness by showing that he was speaking outside his area of expertise (Van Norman is not a clinical researcher). He reiterated the claim that TMAP never dictated what a physician could or could not do ('And to be clear, Doctor, you're not suggesting to this jury that you would ever not give a patient what you thought was the appropriate medication just because you had to fill out some additional paperwork, are you?'). He got the witness to state that he currently does sometimes use Risperdal in his practice; and he attempted to discredit the CATIE and CUtLASS studies.

Janssen's Reimbursement Department Takes the Stand

When I first began visiting pharmaceutical companies, I was baffled by the size of their departments called 'Government Affairs' or

something similar. I understood that regulatory matters were complex and important to those companies, but I was not clear why dealing with them would require departments that large. Eventually I realized that government affairs departments were part of and under the supervision of marketing, as indeed has come to be the case with every other function in most pharmaceutical companies, including R&D. The close links between federal and state regulatory agencies and the pharmaceutical industry illustrate the clientelist side of the system.

The first deposition played on 12 January 2012 had been recorded earlier by Ms Nancy Bursch-Smith, and it pointed to those close links. Her job was to manage the relationship between J&J and the Texas Department of Mental Health and Mental Retardation (TMHMR).

The attorney for the state quoted J&J documents that said: '[We] put Steve Shon on the map'. (Steven Shon, described above, was the director of TMHMR during the TMAP years.) Bursch-Smith responded: 'I think that there are many companies that probably were involved with Dr Shon. I wouldn't say that Janssen held that title'. Her answer indicates that Shon was probably receiving money and gaining notoriety through his relationship with a number of SGA manufacturers.

Bursch-Smith was a member of the curiously named 'reimbursement' department. Because so much of the discussion surrounded the origin and dollar amount of checks written to Steven Shon, John Rush and others on the TMAP advisory board, one could think that a reimbursement department is the place that handled the associated paperwork. However, reimbursement actually referred to Medicaid, and Bursch-Smith's job was to figure out how to divert as many Medicaid reimbursement dollars as she could to J&J. The checks written to Shon and the other TMAP advisors were money J&J were laying out in exchange for those 'deliverables' that the trial was intended to uncover.

Bursch-Smith's inability to recall just about anything was little help to her, because the lawyer for the plaintiff had emails detailing how, in exchange for its money to Shon and Rush, J&J sought 'a favorable positioning for Risperdal'. Internal emails bearing Bursch-Smith's name or authorship also showed that J&J were not the only drug company vying for Steve Shon's affections. One email that Bursch-Smith received contained the words, 'Lilly [another big drug company] is sending their corporate jet to get [Shon] . . . You didn't sell our benefits to Shon'. Cross-examination by the defence sought to affirm Bursch-Smith's claim that J&J was not 'selling' to Shon but

were involved only in an 'exchange of information'. Bursch-Smith's 'redescription' (A. Applbaum 2000) of the first in terms of the second, just as many before her called advertising 'education', reflects once again the simultaneous distinction between, and blurring of, corruption and marketing clientelism. Was the witness hiding behind the overlap, redescribing corruption as normal clientelism, or could she actually not tell the difference?

> Defence Lawyer: Why don't you believe that Janssen influenced Shon's work?
> Bursch-Smith: Because they told us they'd be making their own decisions.

The next witness was Bill Struyk, J&J's Regional Director for State Affairs for seven years.

> Plaintiff Lawyer: You were on the ground floor of the reimbursement team. What was your product?
> Struyk: Risperdal was our primary focus.
> Lawyer: [Takes out a company document] Among the credits listed as your accomplishments [is]: 'Instrumental in influencing Texas mental health care funding and treatment guidelines'.

Those guidelines are the Tri-University Schizophrenia Practice Guidelines, compiled by Allen Frances, John P. Docherty and David A. Kahn, described above. An account of the inception of the Guidelines is in Sharav (2011).

Struyk preferred to use 'education' to describe the original Tri-University symposium in 1996 as well as other activities involving Steven Shon and TMAP-allied psychiatrists. The state's attorney asked Struyk if his department's activities were directed towards increasing sales of Risperdal with the aid of the guidelines. Impatient with the questioning, Struyk twice said, in a tone of jaded irony, 'If it increased sales we were not disappointed'. The cross-examination by the defence allowed Struyk to rephrase his team's purpose: 'Our group's mission was to remove hurdles . . . Our job was to educate on mental health and to make sure drugs were available to those who needed it'.

Still pursuing the subject of funding for TMAP, the plaintiff next called the former head of the Robert Wood Johnson Foundation (RWJF), Dr Stephen Schroeder. That foundation is one of the two largest health and healthcare philanthropies in the United States, and it contributed the largest single amount in financial support of the development of TMAP. Schroeder said he did not believe that TMAP was a 'marketing effort' and he was never contacted by J&J.

The state attorney's presentation of excerpts of Schroeder's deposition began with the lawyer on the tape pointing out that J&J is the single largest financial stakeholder in RWJF. Three of the Foundation's 2009 Board of Trustees members were J&J executives.

> Plaintiff Lawyer: [I understand that] TMAP was an unusual [project for RWJF].
> Schroeder: Our projects generally didn't get into clinical condition.
> Lawyer: Why'd you make an exception in this case?
> Schroeder: I just thought the upside was really – really large.
> Lawyer: Did RWJF do due diligence into the motives of the TMAP people?
> Schroeder: We didn't look into their hearts.
> Lawyer: How about whether they [were taking] money from pharma.
> Schroeder: Well, it happens all the time. That is, most academics actually take money from the pharmaceutical industry for speaking and for travel and dinners and things like that.

The final witness was Percy Coard II. Coard started working as a drug representative for J&J and Risperdal in 1998, served as district manager from 1999 to 2002 and was then promoted to the reimbursement department.

> Plaintiff Lawyer: [reading from Coard's CV] 'Seek out additional individuals and find their importance to the system . . .' Did you understand this was among the activities you were supposed to be engaging in connection with the part of your job relating – relating to your role in 'influencing others'?
> Coard: Yes, sir.

'The system' that the lawyer mentioned referred to several entities, including hospitals, the prison system and TMHMR, where Coard had contact with Steven Shon on a regular basis. Coard described Shon and Miller as key opinion leaders.

The state's lawyer reviewed a 2002 business plan at J&J. It specified a 'threat' to continued growth: Texas Medicaid, which was third in the country on Medicaid spending, was looking to implement cost containment measures. One measure identified in the document was 'prior authorization', which means that before a 'consumer' can see a specialist or receive a specific service or treatment, the request has to pass through a layer of approval involving the payer, such as an insurance company. Medicaid is public insurance. Under the heading 'TMAP Ownership!!! – (ongoing)', the business plan suggested that TMAP and strong advocacy support would lessen the threat of prior authorization.

The discussion turned to the company's effort to place Consta, J&J's long-acting injectable version of Risperdal, 'in a favourable position in TMAP'. Coard explained how helpful Steve Shon was to him in figuring out the best way to get Consta to succeed on the market:

> Dr Shon felt a key to successfully launching Consta in Texas was to focus on in-patients. He said that it is rare for stable patients to be switched from one antipsychotic to another when they enter their community mental health centre.... They typically stay on what they were prescribed as an in-patient. Therefore it's imperative to drive utilization in the in-patient facilities.

Conclusion

The Risperdal case was not overly complicated to try. There were many obvious infractions and J&J had little interest in allowing a media circus to continue at their expense. As it turned out, despite the conclusive evidence of fraud, J&J settled out of court for $158 million, about a quarter of the original demand. This is a small amount when compared with the profits that companies make and with the bonuses given to executives who have already moved on and who are rarely, if ever, held criminally responsible for their actions. Criminal prosecutions and suits, then, are weak tools for constraining off-label marketing.

Although the evidence was fairly clear in the case I have described, as a rule off-label promotion is difficult to prosecute and to halt. Some of the reasons for this are laid out in Figure 1.1, and they may be divided into the proximate and the overarching. Proximate causes are acts of commission or omission taken by companies and prescribing clinicians that, from a legal standpoint, end up muddying, inadvertently or purposefully, the evidence of fraud. Overarching causes are features of the political- and cultural-economic environment that either encourage or legitimate the disputed behaviours.

Taken together, these causes reflect some of the questions raised in the Introduction to this volume and elsewhere, such as the changing relationship between the economic acquiring of wealth and the social playing by the rules that concerned E.P. Thompson (1971) in his description of the English crowd, and the degree to which economic rationality should be applied to areas of life considered vital to people's survival, such as food and medicine.

System of corruption: The practice is so widespread as to be considered the norm rather than the exception.

Legal obstacles: Company strategic documents, including those pertaining to clinical trials, are considered proprietary. Revelatory evidence about the practice generally comes from whistle-blowers within the company, whose motivations are regarded as suspect by juries.

Ghostwriting: Promotions often masquerade as disinterested science, published in reputable medical journals and disseminated to doctors by pharmaceutical reps.

Key opinion leaders: Drug and device manufacturers employ tens of thousands of reputable physicians to act as surrogate marketers and promoters of off-label uses.

Blurred boundary between education and propaganda: Related to ghostwriting, but extends also to Continuing Medical Education, disease-explaining media (brochures, websites, radio shows), informational seminars led by key opinion leaders and funded by industry.

Partial truths: Many off-label uses of drugs (whether illicitly promoted or not) prove to be medically justified, and so physicians are not quick to be suspicious of or criticize off-label promotions.

Tenuous science: Off-label promotions are most common in areas of medicine where outcomes of the procedure or treatment are ambiguous, such as psychiatry (and spinal fusion surgery).

Physician over-confidence in their own judgment and obstinate in their belief that they know all about, and so are impervious to, drug company influence.

Poor adverse event reporting: Independent research into drug safety is usually too late to catch bad practices, while physicians report only 1–5 per cent of adverse events (Healy 2012b).

Political ideology: The notion that the free market is self-correcting and always right. The drug lobby in the US Congress assures a legal attitude lenient towards companies.

Figure 1.1 Reasons why off-label promotion schemes are difficult to halt

Off-label promotion is an economic activity that happens to violate federal regulations. For those within the sector, however, it is not deviant. The testimony I have described shows how pervasive and complicated it can be in the pharmaceutical industry, and likely in any industry that is so much focused on marketing. Sometimes this sort of activity is easily visible, such as in print advertisements or on product websites. It is more difficult to identify when drug representatives talk to physicians during office sales calls or over expensive dinners, or when doctors who are paid consultants of drug companies speak at conferences or in Continuing Medical Education venues. Even more difficult to discern is the effect of rigged studies published in leading journals,

which are often reprinted and disseminated widely to physicians around the world.

The trial of the J&J suit that I have described illustrates the overlap of marketing clientelism and corruption, for even the most florid of J&J's actions can be located easily on the continuum of pharmaceutical marketing practices. While the actions under investigation may be legal contraventions, they are not managerial ones. On the contrary, the marketing practices conform to business and organizational norms that are embraced as sound management. This helps to account for the fact that the activities that lead to prosecution are distinguished, if at all, by degree and not kind from other practices. If for no other reason than that competitive pressures drive companies to behave in similar ways, the marketing strategies and tactics for drugs of any given class will resemble each other. So, when Vioxx was implicated in a vast scheme of marketing fraud, including off-label promotions, industry watchers knew that the other Cox-2 inhibitors (Celebrex and Bextra) were unlikely to be far behind. Similarly, when Zyprexa (Lilly's SGA) was called to account, informed observers concluded that the other manufacturers of SGAs were guilty of similar crimes, which would become visible if the opportunity arose to subpoena their marketing records.

What I have said of Medtronic, J&J and the rest buttress a point I made earlier in this chapter. That is, the neoliberal stress on the free market can lead firms to market freely. In the case of various pharmaceutical firms, this means creating a market demand when there was none, even if it involves engaging in practices that most people would think are highly questionable. In the words 'most people', however, lies another point that I have made, one that also bears on the arguments made in the Introduction to this volume, relating to the concept of deviance. That is, the sort of practices that I have described are taken for granted within the industry, a point demonstrated by some of the testimony that I have quoted in this chapter.

Deviance, then, resembles interpretation of the results of scientific studies of drugs: those who seek simple yes-or-no answers are likely to be disappointed. Vis-à-vis marketing, practices that are deviant for some may be normal for others, and those practices may be so pervasive that, without them, the operation of significant areas of life would come to a halt, at least until new practices and procedures emerge.

As discussed in the Introduction, in complex and diverse societies, it is likely that different sets of people will see different things as deviant, just as they will see different things as wrong. Reconciling

these is the function of politics and government, so that the concern with economic practices of the sort that exist in the pharmaceutical industry needs to be joined with a concern with political judgement and the factors that shape it.

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Notes

1. A description of how Shon allegedly peddled TMAP in Pennsylvania is in Jones (2004), and Jones is the whistle-blower who originally filed the suit against J&J in 2004 (see also Waters 2005).
2. Some well-placed anthropologists also appear to have embraced it (see Healy 2012b).

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