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Abstract

This essay reviews work in sociology and cognate fields regarding pharmaceutical marketing and its regulation. In particular, it considers how this literature contributes to a better understanding of the process of pharmaceuticalization, defined as "the translation or transformation of human conditions, capabilities, and capacities into opportunities for pharmaceutical intervention." The review addresses two research areas that offer productive avenues of investigations of the marketing-regulatory nexus in the context of pharmaceuticalization. The first concerns the sociopolitical mechanisms underlying development and enforcement of marketing rules. The second considers the impact of rules and enforcement schemes on corporate marketing practices and, consequently, on the shaping of pharmaceutical markets and health.

Introduction: pharmaceuticalization and the marketing–regulatory nexus

This essay reviews work in sociology and cognate fields regarding pharmaceutical marketing and its regulation. Sociologists have studied the sociopolitical relations of pharmaceutical production, development, and consumption since at least the mid 1980s (e.g. Braithwaite 1984; Gabe and Bury 1988). However, interest in pharmaceuticals has grown considerably in recent years, reflecting the pivotal role of pharmaceuticals and their manufacturers in society (see Sismondo 2004; Conrad 2005; Busfield 2006; Williams et al. 2008; Williams et al. 2011; Abraham 2008; Abraham 2010 for a range of useful entry points into this literature). One key concept in this context is pharmaceuticalization, defined by one group of writers as "the translation or transformation of human conditions, capabilities, and capacities into opportunities for pharmaceutical intervention" (Williams et al. 2011, p. 711). Although related to the sociological concept of medicalization (Conrad 1992), pharmaceuticalization is different because it refers not to the expansion of diagnoses or medical jurisdiction but to the shaping of markets for drugs produced and sold by pharmaceutical companies.

In this context, pharmaceutical industry marketing is frequently cited as an important driving force (Brody and Light 2011; Abraham 2010; Davis and Abraham 2011; Dumit 2012; Dukes et al. 2014; Busfield 2015). Pharmaceutical industry marketing ranges from the obvious in the form of advertisements, commercials, and the activities of company sales representatives who visit doctors' offices to the more covert in the form of coordinated marketing campaigns masquerading as educational or scientific activities, such as industry-organized conferences and some clinical studies (Angell 2004). However, while both obvious and covert marketing schemes are popular targets for sociological analyses, the development, enforcement, and outcome of rules—supposedly in place to ensure that promotional information and marketing activities support appropriate use of medicines—remain comparatively less studied. Yet social scientists repeatedly point to the crucial role of the regulatory dimension in shaping drug markets, since rules both formally and practically constrain the conduct

of actors—including commercial operations within the industry (Braithwaite 1984; Abraham 1994; Abraham and Lewis 2000; Mossialos et al. 2004; Daemmrich 2004; Dukes 2006; Epstein 2007; Carpenter 2010; Davis and Abraham 2013a; Tobbell 2012, Dukes et al. 2014; Cloatre and Pickersgill 2014).

Against this background, the aim of this paper is to review the literature on the pharmaceutical marketing-regulatory nexus, focusing on two broad areas of research that provide insight into the shaping of pharmaceutical markets: (i) the sociopolitical mechanisms underlying development and enforcement of marketing rules, and (ii) the impact of marketing rules and enforcement schemes on corporate practices and, in this way, their ability to influence the shaping of pharmaceutical markets and health. Put differently, the aim is to show how rules and associated enforcement schemes—or "regulatory regimes" (Hood et al. 2001)—governing drug marketing can effectively be regarded as both dependent and independent variables in scholarly analyses.

I begin by discussing how pharmaceutical companies use a range of marketing practices in an effort to shape markets for their products, which raises questions about the appropriate regulation of such practices. The regulatory dimension is then reviewed by considering regulatory regimes first as dependent and then as independent variables. Since most studies on the pharmaceutical marketing-regulatory nexus known to this author pertain to Western countries, a caveat of this review is its limitation to contexts characterized by a strong "regulatory state" (Majone 1994). That is, contexts with "a panoply of national and international regulatory frameworks, institutions, and mechanisms to correct for various forms of market failure (Rothstein et al. 2006, p. 94)," including health and societal risks associated with pharmaceutical drugs.

Note on terminology

Throughout the text, a distinction is made between advertising, promotion, and marketing. Advertising calls attention to a product in a public medium. Promotion, a more general term, describes activities aimed at increasing sales. In addition to advertising, the latter includes personal contacts with patients or prescribers. Finally, marketing refers to all activities that align products and consumers; it includes promotion but, in the present case, may also involve public relations, as well as conducting and disseminating medical research (Sismondo 2004; Steinman et al. 2006). Throughout, a distinction is also made between laws, regulations, and standards. Laws are rules passed by a legislative body, such as a country's parliament. Based on the interpretation of such laws, regulators—usually governmental bodies—formulate regulations that are the specific requirements that need to be followed. Standards, finally, refer to the rules adopted by any organization, such as voluntary ethical standards approved by a company or industry trade association.

Industry marketing and shaping of pharmaceutical markets

The pharmaceutical industry and the medical establishment are likely to argue that the growth in medicines use in recent decades is largely due to the capacity of science to discover pharmaceutical solutions to new or established illnesses. Sociologists have broadly rejected this argument by countering that drug innovations offering significant or major therapeutic advance have actually been declining, including within areas of major health need (e.g. Abraham 2010; Busfield 2010; however see, Davis 2015). This claimed lack of therapeutic advance has been used to justify the examination of causes other than biomedical progress to explain patterns of pharmaceutical production and consumption, including industry marketing, deregulatory state policies aimed at fostering competitive businesses, the ideology of patients as consumers,

medicalization, and expectations of doctors and patients (Abraham 2010; Williams et al. 2011; Gabe et al. 2015). Crucially, such causes are understood as interrelated. For example, deregulatory state polices, such as privatization, have assisted in the ideological transformation of patient needs into consumer demands (Fotaki 2011). The ideology of patients as consumers has then been used by the industry and allied political interests to support further deregulatory polices, such as attempts to relax rules governing provision of drug information to patients by the pharmaceutical industry (Mulinari 2013; Davis and Abraham 2013a).

Sociologists have also pointed to the importance of various social actors in these inter-connected processes (Busfield 2010). The literature implicates not only pharmaceutical com-panies but also the state, regulators, clinicians, patient organizations, the media, and managed care and health insurers for their roles in contributing to pharmaceuticalization (and more rarely de-pharmaceuticalization), albeit to varying degrees (e.g. Elbe et al. 2015; Britten et al. 2015; Hogarth 2015). However, because of its obvious interest in market shaping to bolster sales, the role of industry has come under increasing scrutiny (Abraham 2002; Busfield 2010). Over the years, studies have pointed to the numerous and sometimes malevolent ways through which companies bolster sales, sometimes even in the absence of therapeutic innova-tion. The list includes—but is not limited to—providing financial support to patient groups that support industry agendas (Jones 2008; Davis and Abraham 2013a) and to professionals acting as so-called "key opinion leaders" within specific medical subfields (Sismondo 2013).

According to pharmaceuticalization scholars, one key way in which pharmaceutical compa-nies shape markets is by hyping product expectations in order to create "communities of hope" to prescribe and consume their drugs (Williams et al. 2011). Promotion is an obvious example since the purpose of pharmaceutical promotion is essentially to influence, through promissory claims, how patients, prescribers, and payers view the safety, efficacy, and cost-effectiveness of particular products. Although the exact amount industry spends on promotion remains undis-closed, some data are available for the United States (US), where promotion was estimated at 9% of sales (about $28 billion) in 2010, of which nearly 10% went to Direct-to-Consumer Advertising (DTCA) of prescription drugs (Kornfield et al. 2013). Yet the real figure for total spending on promotion is likely to be significantly higher (Gagnon and Lexchin 2008); the WHO cites about 30% globally (WHO 2014).

Industry representatives assert that promotion, for example advertising, serves to educate patients and doctors about appropriate use of drugs (Francer et al. 2014). However, over the years, industry promotion—especially to patients—has been a recurrent target of criticism because of its alleged undesirable effect on the world-views and behaviors of patients and pre-scribers (Angell 2004; Fisher and Ronald 2008; Applbaum 2009; Padamsee 2011; Donohue 2006; Conrad and Leiter 2008; Fisher and Ronald 2010; Padamsee 2011; Ebeling 2011; Barker 2011; Brody and Light 2011; Dumit 2012). For example, Dumit (2012) has argued that US companies have used drug advertising and "disease awareness" campaigns to generate a "new notion of illness" that views the body as inherently ill rather than healthy, thereby creating a need for life-long pharmacological intervention—a concept that he claims now drives the con-tinual and untenable growth in drugs, diagnoses, and healthcare costs in this country. Yet, while most of this literature explicitly or implicitly depicts industry promotion as creating or manipu-lating individual needs, often with negative consequences for patient health, others contend that it "rather seeks to understand the desires of potential consumers, to affiliate those with their products and to link these with the habits needed to use those products" (Rose 2007, p. 702).

However, while promotion may not necessarily create false needs, as Rose (2007) suggests, it may still create false claims and expectations about the ability of drugs to meet those needs, as pointed out by Abraham (2010). Yet as Davis and Abraham (2013a, p. 15) also acknowledge, "few social science studies make any attempt to systematically investigate the validity of

marketing claims or to distinguish between scientific information or commercial bias, together with what this means for public health" (see also, Abraham 2008). However, some recent analyses have moved in this direction by pointing to inconsistencies between industry information and marketing claims on the one hand, and the scientific evidence on the other, a situation that could lead to medically inappropriate drug utilization (McHenry 2009; Mulinari 2013; Zetterqvist and Mulinari 2013). Such findings are consistent with the growing body of medical and pharmaceutical policy literature that investigates the veracity of advertising claims in medical journals, concluding that claims are often incomplete, inflated, and sometimes downright misleading (reviewed in Othman et al. 2009; see also Othman et al. 2010). The public health relevance of this literature is heightened by other studies addressing the impact of promotion on medical knowledge and practice, which underscore how misleading claims are likely to have negative repercussions on health by endorsing misuse or overuse of drugs (Spurling et al. 2010; Kesselheim, Darby, Studdert, Glynn, Levin and Avorn. 2011; Larkin et al. 2014; Austad et al. 2014; Becker et al. 2011a).

Particularly, revealing evidence of how marketing biases medical knowledge and practice has emerged from a number of high-profile legal cases in the United States where company employees or former employees from many major global companies have acted as "whistleblowers" to uncover illicit activities (Steinman et al. 2006; Ross et al. 2008; Spielmans 2009; Mello et al. 2009; Spielmans and Parry 2010; Kesselheim, Mello and Studdert 2011; Dukes et al. 2014). A widely publicized case involved British drug giant GlaxoSmithKline (GSK), which in 2012, agreed to plead guilty and to pay $3 billion to resolve its criminal and civil liability arising from unlawful drug promotion and failure to report safety data, as well as its civil liability for alleged false price reporting practices (US Department of Justice 2012). Among other things, between 1998 and 2003, GSK unlawfully promoted its antidepressant Paxil (also marketed as Seroxat) to treat depression in patients under age 18, despite emerging evidence that antidepressants increase suicide risk among adolescents. Moreover, GSK participated in preparing, publishing, and distributing a misleading medical journal article that misrepresented a clinical trial of Paxil as demonstrating efficacy in the treatment of depression in patients under age 18, when in fact, the study actually failed to do so (McHenry and Jureidini 2008). The GSK case clearly exemplifies the calculated deceit of certain industry marketing strategies. And it exemplifies another critical point made by various critics of pharmaceutical marketing: the increasingly blurred distinction between industry clinical trials and their marketing efforts (Sismondo 2009; McHenry 2009; Applbaum 2009; Spielmans and Parry 2010; Dumit 2012; Healy 2012).

While the evidence that marketing, especially in the US, has repeatedly distorted medical information and research in ways that have put patient health at risk is therefore irrefutable, critics of industry marketing practices have not been immune to challenge. A typical reaction has been to characterize critics as suffering from "denominator neglect," as discussed by Stossel and Stell (2011), in relation to the alleged dangers of industry bias in academia—i.e. failing to consider that the many cases of proper conduct supposedly dwarf the comparatively few cases that comprise the numerator. On a similar but less critical note, Fisher et al. (2015, p. 3) warned that "pharmaceuticalization literature" could be biased towards a subset of drugs and disorders "because they provide rich examples of the pharmaceutical industry's negative influence on society" while generally ignoring other cases that do not comprise equally good examples of undue industry influence, or—it can also be added—failing to give credit where drugs have clearly addressed previously unmet clinical needs (Kesselheim and Avorn 2013). Sociologists have also been reproached for sometimes depicting the industry as omnipotent controllers of drug markets, where most other stakeholders are either outmaneuvered or even co-opted by industry (Rose 2007). Finally, most of the literature focuses on Western and especially

US-centered corporate marketing practices, although there have admittedly been important attempts to widen the analytical scope (e.g. Hara 2003; Ecks 2005; Lakoff 2005; Bell and Figert 2012; Dukes et al. 2014). Such concerns notwithstanding, this literature has contributed to a greater understanding of the range of marketing tactics—some unmistakably fraudulent and medically risky—that operate at various levels to influence the shaping of drug markets.

Development and enforcement of marketing rules: regulatory regimes as dependent variables

The studies of industry marketing reviewed above have often called either for a tightening of rules governing such activities or for more stringent enforcement of already existing rules, in the interest of public health (e.g. Mintzes 2006; Abraham 2008; Goldacre 2012). Such appeals raise questions about the development and enforcement of rules governing marketing activities, as well as their ability to constrain undue industry influence.

Notably, concerning the former, a number of studies have investigated how pharmaceutical companies and trade associations engage in high-level political lobbying and foster networks and alliances with groups both inside and outside the state apparatus to influence the policies, laws, and regulations relevant to pharmaceutical markets (Gosden and Beder 2001; Abraham 2002; Adamini et al. 2011; Ozieranski et al. 2012; Tobbell 2012). For example, in a series of studies, Abraham and colleagues describe how the pharmaceutical industry has collaborated with political advocates of neoliberal policies since the 1980s to successfully shape US and EU regulatory systems to better align with industry interests by reducing regulatory burdens while strengthening a regulatory environment more responsive to commercial priorities (e.g. Abraham and Lewis 2000; Davis and Abraham 2013a). This includes harmonizing regulatory standards for drug testing across geographical regions, making governmental regulatory agencies increasingly dependent on fees from companies, increasing the extent and flexibility of consultation between companies and regulators, lowering the standards for efficacy and safety documentation for an increasing number of "priority" drugs, and reducing time spent by regulators reviewing drug applications.

In contrast to such detailed investigations of regulation of both drug testing and approval processes as "dependent" variables, scholars—at least outside the US—have paid less attention to the sociopolitical mechanisms underlying development and enforcement of marketing rules. This is unfortunate because companies have reason, at least in principle, to support and adhere to marketing rules since they help build trust in the industry and its products among employees and academic collaborators, as well as among regulators, prescribers, payers, and consumers of medicines (Dukes 2006; Francer et al. 2014). Marketing rules and enforcement schemes exist at various levels (international, regional, national) and may pertain to industry interactions with one or more actors (Francer et al. 2014). Thus, there are laws and regulations at the national level (and supranational for the EU) to cover the promotion of drugs; these may be enforced either through legal action or through medicines regulatory bodies. For example, authorities typically forbid companies to encourage drug use outside the medical indications for which the drug was approved. Many countries also ban DTCA of prescription drugs, as well as misleading drug information. Moreover, many medical associations and employers (e.g. hospitals or universities) have professional or employee Codes of Conduct that cover interactions with industry (Shnier et al. 2013; Epstein et al. 2013; Francer et al. 2014). Numerous medical journals have also developed publication policies to ensure transparency regarding financial conflict of interests among authors (International Committee of Medical Journal 2015). Some individual pharmaceutical companies have internal standards, while the global pharmaceutical trade association (the IFPMA), as well as regional and many national trade associations, have

Codes of Practice that are supposed to ensure that communication and interaction with researchers, physicians, patients, and payers of medicine support high-quality care (Francer et al. 2014).

In fact, in many countries—such as Australia, Canada, Italy, the Netherlands, the United Kingdom (UK) and Sweden—marketing activity is primarily governed by such voluntary codes administered by the pharmaceutical industry's own self-regulation systems (Lexchin 1999; Fox et al. 2006; Doran and Löfgren 2013; Zetterqvist and Mulinari 2013; Alves et al. 2014). A recent comparative study analyzing self-regulation in the UK and Sweden suggested that the regulatory regimes in those countries could best be defined as "delegated self-regulation as an integral part of a co-regulatory scheme involving industry and national medicines regulatory authorities" (Zetterqvist et al. 2015, p. 2). That is, the medicines regulatory authorities—e.g. the UK Medicines and Healthcare products Regulatory Agency (MHRA)—have delegated a significant part of their defined statutory responsibility to the industry trade groups in order to ensure that marketing practices comply with agreed-upon rules. This arrangement differs from the US—and certain other European countries, like France—where governmental regulatory agencies regulate marketing with little or no formal delegation to self-regulatory bodies (Mello et al. 2009; Korenstein et al. 2011; Mintzes et al. 2013). However, even in countries with formal delegation to industry bodies, governmental regulatory agencies may still retain important functions. For example, since 2005, the MHRA has pre-vetted advertisements targeting health professionals for new products, products with safety concerns, or products with major new medical indications. The UK drug regulatory agency is also tasked with investigating potential breaches of advertising legislation, although it strongly recommends the use of the self-regulatory system for complaints concerning companies that have accepted the industry code (Zetterqvist et al. 2015).

Regulation of pharmaceutical marketing can therefore be characterized as internationally divergent, multilayered and "decentered," i.e. involving many actors other than the state (Black 2001). This regulatory complexity reflects the fact that marketing regulatory regimes are outcomes of evolving sociopolitical processes, and as such, they are obvious objects for sociological analysis (Doran and Löfgren 2013). For example, as Conrad and Leiter (2008) explain, permissive US regulations pertaining to DTCA began developing in the 1980s and seemed to have been the work of high-level Food and Drug Administration (FDA) officials, most importantly the FDA Commissioner, who believed patients should have a greater role in choosing treatments (see also, Donohue 2006; Greene and Herzberg, 2010). According to Davis and Abraham (2013a), the FDA Commissioner's view resulted from his marriage of the ideology of consumerism with deregulatory politics, a marriage enabled by the ascendance of neoliberalism in the 1980s. Curiously, the industry did not appear to be enthusiastic about DTCA at first; yet, the FDA subsequently won industry support for deregulatory measures (Davis and Abraham 2013a).

At the same time, however, DTCA of prescription drugs is still banned in most other developed countries, including across the EU, despite pressure from the European industry trade group and aligned "pro-business" interests in the European Commission (Brooks and Geyer 2011; Mulinari 2013). But in the EU, unlike in the US, deregulatory proposals have hitherto encountered successful opposition from a wide range of actors, including industry-independent patient organizations, health professionals, and perhaps most importantly, the European Commission's health and consumer branch and individual EU member states that fear a permissive legal framework would increase drug costs. A take-home message from the industry's failed efforts to legalize DTCA in Europe is that countervailing forces, including state and non-state actors, can sometimes effectively challenge the deregulatory agenda (Mulinari 2013). Such success is consistent with Doran and Löfgren's (2013) suggestion that the pharmaceutical

industry has proved less capable of shaping the regulation of marketing than other areas of pharmaceutical policy because drug promotion is relatively more open to debate and activism.

Outcome of marketing rules: regulatory regimes as independent variables

The above discussion considered rules and enforcement schemes as outcomes to be explained, as dependent variables in which, for example, consumerist ideology serves as an independent or explanatory variable. However, in order for regulatory regimes to be relevant when analyzing the shaping of drug markets, it also seems necessary to consider them as "independent" variables, as has successfully been done in other areas of pharmaceutical regulation (Abraham and Davis 2009). That is, it is necessary to explain how rules and their enforcement (or lack thereof) impact corporate practices to influence the pattern of drug consumption and, consequently, health.

Indeed, the notion of marketing regulations as independent variables is central to social science and policy debates on pharmaceuticals. For example, Conrad and Leiter (2008) have accused the FDA's permissive policies regarding DTCA of being at least partly responsible for the alleged medically unjustifiable increase in the use of drugs in the US, although others point to similar trends in comparable countries where DTCA for prescription drugs is banned (Abraham 2010). Concerns about the negative effects of DTCA on health have also been raised in New Zealand, where the practice is also allowed (Hoek and Maubach 2005), although industry representatives assert that such concerns are effectively addressed by the independent pre-vetting of all consumer ads (Sheehy 2014).

There is also debate on the health consequences of the FDA's apparent failure to enforce marketing rules more generally, as demonstrated by the growing number of legal cases showing how companies systematically planned and carried out partially illegal marketing campaigns to effectively increase drug sales (Kesselheim, Mello and Studdert 2011; Lexchin and Kohler, 2011; Landefeld and Steinman 2009). Thus, as was pointed out by the US Government Accountability Office in its investigation of the FDA's oversight of so-called off-label promotion, many deceptive and complex marketing schemes were completely unknown to the FDA before they were investigated by the Department of Justice, many years after the fact, following complaints by company whistleblowers (GAO 2008).

The FDA's failure to detect and regulate illegal industry marketing practices is to some degree offset by comprehensive Department of Justice investigations based on whistleblower complaints, which have resulted in escalating monetary penalties for pharmaceutical companies, as well as major financial rewards for whistleblowers (Kesselheim, Mello and Studdert 2011). However, although the penalties levied in the US may seem massive, they may still be too low to deter illicit marketing, as suggested by the absence of long-term effects on the value of company stocks and the profitability of illicit activities (Kesselheim et al. 2011; Matthews 2013). A further problem is that criminal investigation and prosecution typically take years, during which time illicit marketing schemes may continue uncensored (Davis and Abraham 2013b).

Similarly, there is a longstanding debate on the merits and shortcomings of industry self-regulation with respect to its ability to ensure compliance with marketing rules and, hence, support quality prescribing. According to its proponents, self-regulation should have numerous advantages over conventional state regulation, including speed and flexibility (Francer et al. 2014). Further, because self-regulation is based on Codes of Practice, which are often more far-reaching than legal provisions, this approach may improve industry behavior (Dukes et al. 2014). It has even been suggested that industry may refrain from illicit promotion in Europe —unlike in the US—because the wider involvement of industry in policing marketing in

Europe encourages companies to comply with rules and deters illicit conduct (Osborn 2010). In particular, companies may want to comply with voluntary codes to prevent implementation of future or additional state legislation (Francer et al. 2014).

In practice however, critics say self-regulation often fails to live up to its theoretical promise (Lexchin 2003; Lexchin 2012; Doran and Löfgren 2013). Accordingly, studies have documented discrepancies between the ethical standard codified in Codes of Practice and the actual conduct of companies in some countries (House of Commons Health Committee 2005; Arnold and Oakley 2013; Zetterqvist and Mulinari 2013; Alves et al. 2014; Zetterqvist et al. 2015). For example, the 2005 House of Commons Health Select Committee's report on the influence of the pharmaceutical industry in the UK expressed concerns about lax oversight over medicines promotion, substantial lags in the self-regulatory system that allow firms to continue running misleading advertisements for extended periods of time, and insufficient sanctions that fail to deter companies from providing unreliable information. More recently, a systematic study of reported marketing violations 2004–2012 found that companies in the UK and Sweden were reprimanded for breaching the industry code on average more than once per week in each country (Zetterqvist et al. 2015). Nearly 20% of the violations in both countries were serious breaches, such as marketing for an unlicensed indication and marketing of prescription drugs to patients, both illegal in the EU.

As argued by Vilhelmsson et al. (2015), the deterrent capacity of regulatory systems depends on a credible threat of detection coupled with efficient and appropriate sanctions following exposure of wrongdoing. Self-regulatory systems rely largely on complaints from company outsiders, particularly competing companies, and, thus, differ from the US scheme for detecting marketing violations, where financial rewards are used to incentivize whistleblowers to help uncover illicit marketing and fraud. Consequently, self-regulatory systems may be severely limited in their ability to uncover complex marketing schemes that are concealed from company outsiders. Regarding the question of appropriate sanctions, Zetterqvist et al. (2015) point out that violating companies in the UK and Sweden pay very low fines that are not intended to be a financial deterrent. Instead fines are designed to recover the cost of processing complaints and administering the self-regulatory system. According to Zetterqvist et al. (2015), such circumstances cast doubts on the ability of the current balance between self-regulation and legislative control with government oversight to sufficiently and adequately safeguard against illicit marketing in those countries.

Conclusions and future directions

Research in recent decades has revealed how the industry exerts a strong influence over pharmaceutical markets, while simultaneously showing how various factors curtail industry power. The internationally divergent and complex marketing regulatory regimes supposedly in place to ensure that companies follow agreed-upon rules are a potentially strong social factor in this respect. Yet, the prevalence and severity of industry misconduct suggests at least partial regulatory failure. Evidence of such regulatory failure comes both from countries where government regulatory agencies directly regulate promotion (e.g. the US) and countries with major delegation of regulatory duties to industry bodies (e.g. the UK). The debate will therefore surely continue on how to achieve corporate compliance and ensure protection from undue industry influence. In particular, critics of pharmaceutical marketing are likely to contend that the examples of regulatory failure and dubious marketing practices are merely the "tip of the iceberg" (e.g. McHenry 2009), while defenders of industry marketing practices will contend that such critics fail to recognize that in most instances companies adhere to the rules and promote medically appropriate use of medicines (e.g. Stossel and Stell 2011).

Such controversies suggest the need to further investigate the regulation of industry marketing. Due to the co-evolving nature of regulatory regimes and corporate marketing strategies, it would also seem imperative to remain vigilant for potentially important developments in this field. This includes novel government, funding agency, journal, and corporate policies that claim to increase transparency regarding industry–physician interactions (Pham-Kanter 2014), financial conflict of interests (Chew et al. 2014), and clinical trials (Groves 2014). In sociology, such studies hold promise for shedding further light on the pharmaceuticalization process by allowing analysts to assess the relevance and relationship of various factors such as consumerism and deregulatory policies, as well as key countervailing forces, for the development and enforcement of marketing rules. But studies of the marketing-regulatory nexus should also increasingly focus on how regulatory regimes constrain (or fail to constrain) marketing tactics and, in this way, influence the shaping of pharmaceutical markets and health outcomes in different countries. Such studies may also serve as the basis for suggestions to reform regulatory arrangements in an effort to improve the quality of medical information and prescribing.

Short Biography

Shai Mulinari is a multidisciplinary researcher based at the Department of Sociology at the Faculty of Social Sciences and the Unit of Social Epidemiology at the Department of Clinical Sciences at Lund University in Sweden. He has also been a Visiting Research Fellow at the Department of Social Science, Health and Medicine, King's College, London. He started his career in the natural sciences and, in 2008, received his Ph.D. in Developmental Biology from Lund University for work on the genetic control of embryonic development. His current research, however, is located at the intersection of sociology, science and technology studies, pharmaceutical policy and public health; he has authored or co-authored papers in many areas, for example, in Sociology of Health & Illness; Social Science & Medicine; Science & Technology Studies; PLoS Medicine; PLoS ONE; European Journal of Public Health; Philosophy, Ethics and Humanities in Medicine; Journal of the History of the Neurosciences, and Philosophy, Psychiatry & Psychology. A major research interest is in the regulation of the pharmaceutical industry.

Note

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References

Abraham, John. 1994. 'Bias in Science and Medical Knowledge: The Opren Controversy.' *Sociology* **28**: 717–36.

Abraham, John. 2002. 'The Pharmaceutical Industry as a Political Player.' *Lancet* **360**: 1498–502.

Abraham, John. 2008. 'Sociology of Pharmaceuticals Development and Regulation: A Realist Empirical Research Programme.' *Sociology of Health & Illness* **30**: 869–85.

Abraham, John. 2010. 'Pharmaceuticalization of Society in Context: Theoretical, Empirical and Health Dimensions.' *Sociology* **44**: 603–22.

Abraham, John and Courtney Davis. 2009. 'Drug Evaluation and the Permissive Principle: Continuities and Contradictions between Standards and Practices in Antidepressant Regulation.' *Social Studies of Science* **39**: 569–98.

Abraham, John and Graham Lewis. 2000. *Regulating Medicines in Europe: Competition, Expertise and Public Health*. London: Routledge.

Adamini, Sandra, Hans Maarse, Esther Versluis and Donald W. Light. 2009. 'Policy making on data exclusivity in the European Union: From industrial interests to legal realities.' *Journal of Health Politics, Policy and Law* **34**: 979–1010.

Alves, Teresa L., Auramarina F. Martins De Freitas, Martine E. C. Van Eijk and Aukje K. Mantel-Teeuwisse. 2014. 'Compliance of Disease Awareness Campaigns in Printed Dutch Media With National and International Regulatory Guidelines.' *PloS One* **9**: e106599.

Angell, Marcia. 2004. *The Truth About the Drug Companies: How They Deceive Us and What to Do About It*. New York: Random House.

Applbaum, Kalman. 2009. 'Is Marketing the Enemy of Pharmaceutical Innovation?' *Hastings Center Report* **39**: 13–17.

Arnold, Denis G. and James L. Oakley. 2013. 'The Politics and Strategy of Industry Self-Regulation: The Pharmaceutical Industry's Principles for Ethical Direct-to-Consumer Advertising as a Deceptive Blocking Strategy.' *Journal of Health Politics, Policy and Law* **38**: 505–44.

Austad, Kirsten E., Jerry Avorn, Jessica M. Franklin, Eric G. Campbell and Aaron S. Kesselheim. 2014. 'Association of Marketing Interactions With Medical Trainees' Knowledge About Evidence-Based Prescribing: Results From a National Survey.' *JAMA Internal Medicine* **174**: 1283–90.

Barker, Kristin K. 2011. 'Listening to Lyrica: Contested Illnesses and Pharmaceutical Determinism.' *Social Science & Medicine* **73**: 833–42.

Becker, Annette, Fatma Dörter, Kirsten Eckhardt, Annika Viniol, Erika Baum, Michael M. Kochen, Joel Lexchin, Karl Wegscheider and Norbert Donner-Banzhoff. 2011. 'The Association Between a Journal's Source of Revenue and the Drug Recommendations Made in the Articles it Publishes.' *Canadian Medical Association Journal* **183**: 544–48.

Bell, Susan E. and Anne E. Figert. 2012. 'Medicalization and Pharmaceuticalization at the Intersections: Looking Backward, Sideways and Forward.' *Social Science & Medicine* **75**: 775–83.

Black, Julia. 2001. 'Decentring Regulation: Understanding the Role of Regulation and Self-Regulation in a 'Post-Regulatory' World.' *Current Legal Problems* **54**: 103–46.

Braithwaite, John. 1984. *Corporate Crime in the Pharmaceutical Industry*. London: Routledge & Kegan Paul.

Britten, Nicky, Sarah Denford, Faith Harris-Golesworthy, Steph Jibson, Nigel Pyart and Ken Stein. 2015. 'Patient involvement in drug licensing: A case study.' *Social Science & Medicine* **131**: 289–96.

Brody, Howard and Donald W. Light. 2011. 'The Inverse Benefit Law: How Drug Marketing Undermines Patient Safety and Public Health.' *American Journal of Public Health* **101**: 399–404.

Brooks, Eleanor, and Robert Geyer. 2012. 'From DTCA-PD to patient information to health information: the complex politics and semantics of EU health policy.' *Journal of Evaluation in Clinical Practice* **18**: 1235–40.

Busfield, Joan. 2006. 'Pills, Power, People: Sociological Understandings of the Pharmaceutical Industry.' *Sociology* **40**: 297–314.

Busfield, Joan. 2010. ''A Pill for Every Ill': Explaining the Expansion in Medicine Use.' *Social Science & Medicine* **70**: 934–41.

Busfield, Joan. 2015. 'Assessing the Overuse of Medicines.' *Social Science & Medicine* **131**: 199–206.

Carpenter, Daniel P. 2010. *Reputation and Power: Organizational Image and Pharmaceutical Regulation at the FDA*. Princeton: Princeton University Press.

Chew, Mabel, Catherine Brizzell, Kamran Abbasi and Fiona Godlee. 2014. 'Medical Journals and Industry Ties.' *British Medical Journal* **349**: g7197.

Cloatre, Emilie and Martyn Pickersgill. 2014. 'International law, public health, and the meanings of pharmaceuticalization.' *New Genetics and Society* **33**: 434–49.

Conrad, Peter. 1992. 'Medicalization and Social Control.' *Annual Review of Sociology* **18**: 209–32.

Conrad, Peter. 2005. 'The Shifting Engines of Medicalization.' *Journal of Health and Social Behavior* **46**: 3–14.

Conrad, Peter and Valerie Leiter. 2008. ''From Lydia Pinkham to Queen Levitra: Direct-to-Consumer Advertising and Medicalisation.' *Sociology of Health & Illness* **30**: 825–38.

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

Davis, Courtney. 2015. 'Clarity, constructive debate and progress in developing methodological and conceptual frameworks for understanding pharmaceuticalization: A reply to Abraham.' *Social Science & Medicine* **131**: 218–20.

Davis, Courtney and John Abraham. 2011. 'Rethinking Innovation Accounting in Pharmaceutical Regulation.' *Science, Technology & Human Values* **36**: 791–815.

Davis, Courtney and John Abraham. 2013a. *Unhealthy Pharmaceutical Regulation: Innovation, Politics and Promissory Science*. Basingstoke: Palgrave Macmillan.

Davis, Courtney and John Abraham. 2013b. 'Is there a cure for corporate crime in the drug industry.' *British Medical Journal* **346**: f755.

Dukes, Graham. 2006. *The Law and Ethics of the Pharmaceutical Industry*. Amsterdam: Elsevier.

Dukes, Graham, John Braithwaite and James P. Moloney. 2014. *Pharmaceuticals, Corporate Crime and Public Health*. Cheltenham, UK: Edward Elgar.

Dumit, Joseph. 2012. *Drugs for Life: How Pharmaceutical Companies Define Our Health*. Durham, NC: Duke University Press.

Donohue, Julie. 2006. 'A history of drug advertising: the evolving roles of consumers and consumer protection.' *Milbank Quarterly* **84**: 659–99.

Doran, Evan and Hans Löfgren. 2013. 'Drug promotion in Australia: Policy contestation and the tightening of regulation.' *Australian Review of Public Affairs* **11**: 19–41.

Ebeling, Mary. 2011. "Get with the Program!': Pharmaceutical Marketing, Symptom Checklists and Self-Diagnosis.' *Social Science & Medicine* **73**: 825–32.

Ecks, Stefan. 2005. 'Pharmaceutical citizenship: Antidepressant marketing and the promise of demarginalization in India.' *Anthropology & Medicine* **12**: 239–54.

Elbe, Stefan, Anne Roemer-Mahler and Christopher Long. 2015. 'Medical countermeasures for national security: A new government role in the pharmaceuticalization of society.' *Social Science & Medicine* **131**: 263–71.

Epstein, Andrew J., Susan H. Busch, Alisa B. Busch, David A. Asch and Colleen L. Barry. 2013. 'Does Exposure to Conflict of Interest Policies in Psychiatry Residency Affect Antidepressant Prescribing?' *Medical Care* **51**: 199–203.

Epstein, Steven. 2007. *Inclusion: the Politics of Difference in Medical Research*. Chicago: University of Chicago Press.

Fisher, Jill A., Marci D. Cottingham and Corey A. Kalbaugh 2015. 'Peering Into the Pharmaceutical 'Pipeline': Investigational Drugs, Clinical Trials, and Industry Priorities.' *Social Science & Medicine* **131**: 322–30.

Fisher, Jill A. and Lorna M. Ronald. 2008. 'Direct to Consumer Responsibility: Medical neoliberalism in pharmaceutical advertising and drug development' Pp. 29–51 in *Patients, Consumers and Civil Society* (*Advances in Medical Sociology*, *Volume 10*), edited by S.M. Chambré and M. Goldner. Brighton, UK: Emerald Group Publishing Limited.

Fisher, Jill A. and Lorna. M. Ronald. 2010. 'Sex, gender, and pharmaceutical politics: from drug development to marketing.' *Gender Medicine* **7**: 357–70.

Fotaki, Marianna. 2011. 'Towards Developing New Partnerships in Public Services: Users as Consumers, Citizens and/or Co-Producers in Health and Social Care in England and Sweden.' *Public Administration* **89**: 933–55.

Fox, Nick, Katie Ward and Alan O'Rourke. 2007. 'A sociology of technology governance for the information age: The case of pharmaceuticals, consumer advertising and the Internet.' *Sociology* **40**: 315–334.

Francer, Jeffrey, Jose Izquierdo, Tamara Music, Kirti Narsai, Chrisoula Nikidis, Heather Simmonds and Paul Woods. 2014. 'Ethical Pharmaceutical Promotion and Communications Worldwide.' *Codes and Regulations Philosophy, Ethics, and Humanities in Medicine* **9**: 2–7.

Gabe, Jonathan and Michael Bury. 1988. 'Tranquillisers as a social problem.' *Sociological Review* **36**: 320–52.

Gabe, Jonathan, Simon J. Williams, Paul Martin and Catherine Coveney. 2015. 'Pharmaceuticals and society: Power, promises and prospects.' *Social Science & Medicine* **131**: 193–98.

Gagnon, Marc-André and Joel Lexchin. 2008. 'The Cost of Pushing Pills: A New Estimate of Pharmaceutical Promotion Expenditures in the United States.' *PLoS Medicine* **5**: e1.

Goldacre, Ben. 2012. *Bad Pharma: How Drug Companies Mislead Doctors and Harm Patients*. London: Fourth Estate.

Gosden, Richard and Sharon Beder. 2001. 'Pharmaceutical industry agenda setting in mental health policies.' *Ethical Human Sciences and Services* **3**: 147–59.

Greene, Jeremy A. and David Herzberg. 2010. 'Hidden in plain sight marketing prescription drugs to consumers in the twentieth century.' *American Journal of Public Health* **100**: 793–803.

Government Accountability Office (GAO). 2008. "FDA's oversight of the promotion of drugs for off-label uses." Available: http://www.gao.gov/assets/280/278832.pdf. Accessed 27 July 2015.

Groves, Trish. 2014. 'Big Strides in Europe Towards Clinical Trial Transparency.' *British Medical Journal* **349**: g6276.

Hara, Takuji. 2003. *Innovation in the Pharmaceutical Industry: The Process of Drug Discovery and Development*. Cheltenham: Edward Elgar.

Healy, David. 2012. *Pharmageddon*. Berkeley: University of California Press.

Hoek, Janet and Ninya Maubach. 2005. 'A model for addressing stakeholders' concerns about direct-to-consumer advertising of prescription medicines.' *European Journal of Marketing* **39**: 1151–65.

Hogarth, Stuart 2015. 'Neoliberal technocracy: Explaining how and why the US Food and Drug Administration has championed pharmacogenomics.' *Social Science & Medicine* **131**: 255–62.

Hood, Christopher, Henry Rothstein and Robert Baldwin. 2001. *The Government of Risk: Understanding Risk Regulation Regimes*. Oxford, UK: Oxford University Press.

House of Commons Health Committee 2005. *The Influence of the Pharmaceutical Industry: Health Select Committee Report Volume 2*. London: The Stationery Office Limited.

International Committee of Medical Journal. 2015. "Conflicts of Interest." http://www.icmje.org/conflicts-of-interest/ Accessed 9 January 2014.

Jones, Kathryn. 2008. 'In Whose Interest? Relationships Between Health Consumer Groups and the Pharmaceutical Industry in the UK.' *Sociology of Health & Illness* **30**: 929–43.

Kesselheim, Aaron S., Devan Darby, David M. Studdert, Robert Glynn, Raisa Levin and Jerry Avorn. 2011. 'False Claims Act Prosecution Did not Deter Off-Label Drug Use in the Case of Neurontin.' *Health Affairs* **30**: 2318–27.

Kesselheim, Aaron S., Michelle M. Mello and David M. Studdert. 2011. 'Strategies and Practices in Off-Label Marketing of Pharmaceuticals: A Retrospective Analysis of Whistleblower Complaints.' *PLoS Medicine* **8**: e1000431.

Kesselheim, Aaron S. and Jerry Avorn. 2013. 'The Most Transformative Drugs of the Past 25 Years: A Survey of Physicians.' *Nature Review Drug Discovery* **12**: 425–31.

Korenstein, Deborah, Salomeh Keyhani, Ali Mendelson and Joseph S. Ross. 2011. 'Adherence of Pharmaceutical Advertisements in Medical Journals to FDA Guidelines and Content for Safe Prescribing.' *PloS One* **6**: e23336.

Kornfield, Rachel, Julie Donohue, Ernst R. Berndt and Caleb Alexander. 2013. 'Promotion of Prescription Drugs to Consumers and Providers, 2001–2010.' *PloS One* **8**: e55504.

Lakoff, Andrew. 2005. *Pharmaceutical Reason: Knowledge and Value in Global Psychiatry*. Cambridge: Cambridge University Press.

Landefeld, Seth C. and Michael A. Steinman. 2009. 'The neurontin legacy — marketing through misinformation and manipulation.' *New England Journal of Medicine* **360**: 103–6.

Larkin, Ian, Desmond Ang, Jerry Avorn and Aaron S. Kesselheim. 2014. 'Restrictions on Pharmaceutical Detailing Reduced Off-Label Prescribing of Antidepressants and Antipsychotics in Children.' *Health Affairs* **33**: 1014–23.

Lexchin, Joel. 1999. 'PMAC code of marketing practices.' *Canadian Medical Association Journal* **160**: 1556.

Lexchin, Joel. 2003. 'Voluntary Self-regulatory Codes: What Should We Expect?' *American Journal of Bioethics* **3**: 49–50.

Lexchin, Joel. 2012. 'Models for Financing the Regulation of Pharmaceutical Promotion.' *Globalization and Health* **8**: 24.

Lexchin, Joel and Jillian C. Kohler. 2011. 'The danger of imperfect regulation: OxyContin use in the United States and Canada.' *International Journal of Risk & Safety in Medicine* **23**: 233–40.

Majone, Giandomenico. 1994. 'The rise of the regulatory state in Europe.' *West European Politics* **17**: 77–101.

Matthews, Susan. 2013. 'Pharma fines increase, but the pain is not felt on Wall Street.' *Nature Medicine* **19**: 5.

McHenry, Leemon B. 2009. 'Ghosts in the machine: Comment on Sismondo.' *Social Studies of Science* **39**: 943–47.

McHenry, Leemon B. and Jon N. Jureidini. 2008. 'Industry-sponsored ghostwriting in clinical trial reporting: A case study.' *Accountability in Research* **15**: 152–67.

Mello, Michelle M., David M. Studdert and Troyene A. Brennan 2009. 'Shifting terrain in the regulation of off-label promotion of pharmaceuticals.' *New England Journal of Medicine* **360**: 1557–66.

Mintzes, Barbara 2006. 'Disease mongering in drug promotion: do governments have a regulatory role?' *PLoS Medicine* **3**: e198.

Mintzes, Barbara, Joel Lexchin, Jason M. Sutherland, Marie-Dominique Beaulieu, Michael S. Wilkes, Geneviève Durrieu and Ellen Reynolds. 2013. 'Pharmaceutical Sales Representatives and Patient Safety: A Comparative Prospective Study of Information Quality in Canada, France and the United States.' *Journal of General Internal Medicine* **28**: 1368–75.

Mossialos, Elias, Monique F. Mrazek and Tom Walley (eds). 2004. *Regulating Pharmaceuticals in Europe: Striving for Efficiency, Equity and Quality*. Maidenhead: Open University Press.

Mulinari, Shai. 2013. 'Regulating drug information in Europe: a pyrrhic victory for countervailing forces?' *Sociology of Health & Illness* **35**: 761–77.

Osborn, John E. 2010. 'Can I Tell You the Truth? A Comparative Perspective on Regulating Off-Label Scientific and Medical Information.' *Yale Journal of Health Policy, Law & Ethics* **10**: 299–356.

Othman, Noordin, Agnes Vitry and Elizabeth E. Roughead. 2009. 'Quality of Pharmaceutical Advertisements in Medical Journals: A Systematic Review.' *PloS One* **4**: e6350.

Othman, Noordin, Agnes Vitry and Elizabeth E. Roughead. 2010. 'Quality of Claims, References and the Presentation of Risk Results in Medical Journal Advertising: A Comparative Study in Australia, Malaysia and the United States.' *BMC Public Health* **10**: 294.

Ozierański, Piotr, Martin McKee and Lawrence King. 2012. 'Pharmaceutical lobbying under postcommunism: universal or country-specific methods of securing state drug reimbursement in Poland?' *Health Economics, Policy, and Law* **7**: 175–195.

Padamsee, Tasleem J. 2011. 'The pharmaceutical corporation and the 'good work' of managing women's bodies.' *Social Science & Medicine* **72**: 1342–50.

Rose, Nikolas. 2007. 'Beyond medicalisation.' *Lancet* **369**: 700–02.

Ross, Joseph S., Kevin P. Hill, David S. Egilman and Harlan M. Krumholz. 2008. 'Guest authorship and ghostwriting in publications related to rofecoxib: A case study of industry documents from rofecoxib litigation.' *Journal of the American Medical Association* **299**: 1800–12.

Rothstein, Henry, Michael Huber and George Gaskell. 2006. 'A theory of risk colonization: The spiralling regulatory logics of societal and institutional risk.' *Economy and Society* **35**: 91–112.

Sheehy, Kevin. 2014. 'DTCA in New Zealand, finding a healthy balance.' *The New Zealand Medical Journal* **1403**: 66–67.

Shnier, Adrienne, Joel Lexchin, Barbara Mintzes, Annemarie Jutel and Kelly Holloway. 2013. 'Too Few, Too Weak: Conflict of Interest Policies at Canadian Medical Schools.' *PloS One* **8**: e68633.

Sismondo, Sergio. 2004. 'Pharmaceutical maneuvers.' *Social Studies of Science* **34**: 149–59.

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

Sismondo, Sergio. 2013. 'Key Opinion Leaders and the Corruption of Medical Knowledge: What the Sunshine Act Will and Won't Cast Light On.' *The Journal of Law, Medicine & Ethics* **41**: 635–43.

Spielmans, Glen I. 2009. 'The promotion of olanzapine in primary care: an examination of internal industry documents.' *Social Science & Medicine* **69**: 14–20.

Spielmans, Glen I. and Peter I. Parry. 2010. 'From evidence-based medicine to marketing-based medicine: evidence from internal industry documents.' *Journal of Bioethical Inquiry* **7**: 13–29.

Spurling, Geoffrey K., Peter R. Mansfield, Brett D. Montgomery, Joel Lexchin, Jenny Doust, Noordin Othman and Agnes I. Vitry. 2010. 'Information from Pharmaceutical Companies and the Quality, Quantity, and Cost of Physicians' Prescribing: A Systematic Review.' *PLoS Medicine* **7**: e1000352.

Steinman, Michael A., Lisa A. Bero, Mary-Margaret Chren and Seth C. Landefeld. 2006. 'Narrative review: the promotion of gabapentin: an analysis of internal industry documents.' *Annals of Internal Medicine* **145**: 284–93.

Stossel, Thomas P. and Lance K. Stell. 2011. 'Time to 'walk the walk' about industry ties to enhance health.' *Nature Medicine* **17**: 437–38.

US Department of Justice. 2012. "GlaxoSmithKline to Plead Guilty and Pay $3 Billion to Resolve Fraud Allegations and Failure to Report Safety Data." http://www.justice.gov/opa/pr/glaxosmithkline-plead-guilty-and-pay-3-billion-resolve-fraud-allegations-and-failure-report. Acessed 9 January 2015.

Tobbell, Dominique. 2012. *Pills, Power, and Policy, The Struggle for Drug Reform in Cold War America and its Consequences.* Berkeley, US: University of California Press.

WHO. 2014. "Pharmaceutical Industry." http://www.who.int/trade/glossary/story073/en/. Accessed 9 January 2014.

Vilhelmsson, Andreas, Courtney Davis and Shai Mulinari. 2015. *Pharmaceutical industry off-label promotion and self-regulation: a document analysis of off-label promotion rulings by the United Kingdom Prescription Medicines Code of Practice Authority 2003–2012.* Lund University: Unpublished working paper.

Williams, Simon J., Jonathan Gabe and Peter Davis. 2008. 'The Sociology of Pharmaceuticals: Progress and Prospects.' *Sociology of Health & Illness* **30**: 813–24.

Williams, Simon J., Paul Martin and Jonathan Gabe. 2011. 'The pharmaceuticalisation of society? A framework for analysis.' *Sociology of Health & Illness* **33**: 710–25.

Zetterqvist, Anna V., Juan Merlo and Shai Mulinari. 2015. 'Complaints, Complainants, and Rulings Regarding Drug Promotion in the United Kingdom and Sweden 2004–2012: A Quantitative and Qualitative Study of Pharmaceutical Industry Self-regulation.' *PLoS Medicine* **12**: e1001785.

Zetterqvist, Anna V. and Shai Mulinari. 2013. 'Misleading Advertising for Antidepressants in Sweden: A Failure of Pharmaceutical Industry Self-Regulation.' *PloS One* **8**: e62609.