

DIRECT TO CONSUMER RESPONSIBILITY: MEDICAL NEOLIBERALISM IN PHARMACEUTICAL ADVERTISING AND DRUG DEVELOPMENT

Jill A. Fisher and Lorna M. Ronald

ABSTRACT

Purpose – This chapter explores the pharmaceutical industry’s strategic utilization of empowerment discourse in two realms: direct-to-consumer advertising (DTCA) and clinical drug development.

Methodology – It draws upon two research projects that examine the role of the pharmaceutical industry in the political economy of healthcare in the United States: Ronald’s policy analysis and participant observation of DTCA policy hearings and Fisher’s participant observation and interviewing of the clinical trials industry.

Findings – Empowerment rhetoric is mobilized by the pharmaceutical industry to create specific expectations about patient-consumer behavior, particularly the responsibilities associated with the consumption of drugs.

Patients, Consumers and Civil Society
Advances in Medical Sociology, Volume 10, 29–51
Copyright © 2008 by Emerald Group Publishing Limited
All rights of reproduction in any form reserved
ISSN: 1057-6290/doi:10.1016/S1057-6290(08)10003-1

Research implications – *The social and economic implications of DTCA and drug trials must be understood within their broader historical and contemporary contexts of health advocacy, consumerism, and medical neoliberalism.*

Practical implications – *The chapter offers alternative constructions of healthcare subjects and pharmaceutical practices that can mitigate the power of the pharmaceutical industry and bring about better pharmaceutical governance.*

Originality/value of chapter – *By analyzing findings from two empirical projects, this chapter is able to shed light on trends in the pharmaceutical industry's discourse about empowerment and consumption from the clinical testing to marketing of new drugs.*

The pharmaceutical industry has effectively appropriated empowerment discourse for its own ends. With origins in health-related social movements, empowerment focused on reclaiming patients' rights to make decisions about and for their bodies (Darvall, 1993; Morgen, 2002). Now, however, empowerment is increasingly redefined in terms of consumption (Grace, 1991; Thomas & Zimmerman, 2007). Although individuals may still feel empowered, the meaning has shifted from equalizing power relations between patients and providers to emphasizing choice of health-related products and services. A greater power imbalance results: between patients and physicians, on one hand, and the pharmaceutical industry, on the other.

This chapter explores the pharmaceutical industry's strategic utilization of empowerment discourse in two realms: direct-to-consumer advertising (DTCA) and clinical drug development. It aims to show how "empowerment" is mobilized to further a particular mode of consumption that creates specific demands on patient-consumers. Empowerment discourse pairs diagnosis, treatment, and compliance with responsibilities that "engaged" healthcare consumers must assume. In the United States Food and Drug Administration (FDA) policy process, narratives construct DTCA as responding to and enabling the transformation of patients into empowered consumers. In clinical trials practice, narratives construct participation in pharmaceutical studies as empowering in spite of the questionable benefits to subjects. This chapter argues that the dominant discourses in DTCA and drug development shape patients' subjectivities as consumers, and it offers alternative constructions of healthcare subjects and pharmaceutical

practices that can mitigate the power of the pharmaceutical industry and bring about better pharmaceutical governance.

BACKGROUND

The rise of a movement contesting the traditional doctor–patient power structure coincided with profound national, political, and economic changes in the United States. Beginning in the 1960s and 1970s, activists and policymakers challenged the established sovereignty of the medical profession (Starr, 1982). The Women’s Health Movement critiqued physicians’ control of information and decision-making (Morgen, 2002). Likewise, in the 1980s, the HIV/AIDS movement further undermined medical authority, advocating for increased patient participation in treatment and research into HIV/AIDS drugs (Epstein, 1996; Chambré, 2006).

During the same time period, the US government – as well as other post-industrialized countries, such as the United Kingdom – attempted to alleviate perceived crises in multiple domains, including energy, healthcare, housing, employment, and the environment, by implementing neoliberal economic policies (Pierson, 1994; Biven, 2001). As a mode of governance, neoliberalism prioritizes free markets and free trade and deprioritizes state provision of social goods. In the 1970s and 1980s, the rhetorical frame of crisis allowed conservatives to usher in domestic and international economic reform by reducing federal funding of public programs and introducing free trade agreements (Harvey, 2005). Neoliberal domestic policies characterize the US systems of welfare (Gilliom, 2001; Schram, 2006), healthcare (Frank, 2002; Fisher, 2007), education (Giroux, 2004; Monahan, 2005), and social security (Niggle, 2003).

Activists and policymakers – both conservatives and liberals – in the 1970s agreed that healthcare was in crisis, even if they disagreed about how to define the problem and its solutions. Regardless of their differences, both groups effectively drew on the rhetoric of progressive social movements. Activists successfully employed the discourse of autonomy and individual rights to change the nature of the doctor–patient relationship, increasing patient information and control over decision-making. However, corporations strategically appropriated the discourse of autonomy and individual rights into their marketing strategies to encourage mass consumption of all types of consumer goods (Talbot, 2000; Cohen, 2003; Rutherford & Gallo, this volume).

Within healthcare, an empowerment discourse was used to underscore the kind of personal responsibility for health deemed necessary for broad policy reform in healthcare delivery (Morgen, 2002). However, empowerment rhetoric can also depoliticize social problems by focusing on individual behavior. For example, the therapeutic culture of “self-help” and related “empowerment” have led women to blame themselves for their own and their families’ experiences of societal problems (Becker, 2005). To the extent that patients have become empowered, this empowerment is mediated by a consumerist, individualized approach to healthcare that reflects and augments the influence of the pharmaceutical industry.

Neoliberal economic policies are evident in the US model of healthcare delivery, where healthcare is not a right guaranteed to citizens but is instead composed of products and services to be purchased by those who can afford them (Shaffer & Brenner, 2004; Fisher, 2008). Even with government programs such as Medicare and Medicaid enabling access to healthcare for the elderly and the poor, uneven availability of diagnostic tests and treatments persists. Moreover, the federal government’s orientation to healthcare highlights their belief that industry can and should profit from their customers’ health and illnesses (Scott, Caronna, Ruef, & Mendel, 2000; Boehm, 2005).

The particular commodification at work casts the conditions of health and illness ever more in terms of products that can be purchased by health-engaged consumers (Elliott, 2003). Described by some scholars as the pharmaceuticalization of healthcare (Nichter & Nichter, 1996; van der Geest, Whyte, & Hardon, 1996; Petryna, Lakoff, & Kleinman, 2006), the US system commodifies not only healthcare delivery but also illness so that individuals’ bodies are fragmented into discrete systems for which there are tailored products. The responsibility to consume those products is passed to patients, so that consumption becomes an obligation if one wants healthcare at all (Monahan & Wall, 2007).

These trends towards commodification are evident in recent shifts in drug marketing and development. Prior to the 1990s, prescription drugs were marketed almost solely to healthcare professionals. However, in the late 1990s, the US FDA changed its guidelines on consumer-directed advertisements to enable widespread broadcast advertising of prescription drugs (Ronald, 2006). In response to pressure from industry, interest groups, and think tanks – as well as a First Amendment challenge to the regulation of pharmaceutical promotion (*Washington Legal Foundation v. Friedman*, 1998) – the FDA reduced the quantity of risk information required in TV advertisements (*Guidance for Industry on Consumer-Directed Broadcast*

Advertisements, 1999). As a result, DTCA exploded, with spending escalating from \$300 million in 1995 to \$3 billion in 2003 (Pines, 1999; Arnold, 2005).

DTCA intensifies commodification by encouraging viewers to choose the newest brand name drugs and by skewing pharmaceutical research priorities to favor drugs with improved consumer characteristics that offer little, if any, clinical improvement over existing treatments (Angell, 2004). For example, the same drug can be rebranded into a drug for a slightly different condition – such as Prozac into Sarafem for premenstrual dysphoric disorder (Greenslit, 2005) – or combined with another drug to create a new brand and, hence, patent. One such combination, Vytarin (a combination of the cholesterol medications Zocor and Zetia) was heavily advertised until research showed that it was less effective than Zocor alone, a drug which is available as a generic at a third of the cost (Associated Press, 2008).

A less visible, but equally problematic, shift in the structure of US healthcare has been the privatization of pharmaceutical clinical development. Since the 1990s, the majority of clinical trials are conducted in the private sector on a contractual basis by private practice physicians who are paid by pharmaceutical companies to recruit their own patients or local community members into drug studies (Bodenheimer, 2000). By outsourcing clinical trials to the private sector, especially to private practices, pharmaceutical companies take their studies directly to existing patient populations around the United States and globally (Fisher, 2007). The majority of new products being developed target illnesses that already have effective treatments available on the market, so studies often attract patients without health insurance who know they need medical attention but may not be able to afford appropriate care (Kolata & Eichenwald, 1999). Most clinical trials provide a limited form of access to the medical establishment during the course of studies and are paid for by the pharmaceutical companies.

Although deploying the language of individual empowerment, the limited types of access that subjects have to medical care is dictated foremost by the needs of the pharmaceutical companies as they design studies to prove that their products are safe and efficacious (Timmermans & Berg, 2003). Patterns of drug development and subject recruitment indicate that pharmaceutical science is centered on identifying the next blockbuster medicine (and commodity) rather than addressing unmet healthcare needs.¹ Moreover, clinical trials provide pharmaceutical companies with a way to pre-market and generate interest in their products: after new drugs are approved for use, the community physicians and patient-subjects are already consumers of those products.

METHODS

This chapter draws upon two research projects that examine the role of the pharmaceutical industry in the political economy of healthcare in the United States. From 2003 to 2006, Ronald carried out qualitative research on DTCA policymaking, including content analysis and participant observation of FDA hearings and interviews with policy actors. She conducted focused content analysis of texts that had been produced to influence the framing of policy problems and solutions, including transcripts from FDA and congressional public hearings; court cases and law review papers; journal articles; media accounts; and policy actors' publications. Together, these materials gave a broad overview of the policy arena, particularly the way that participants shaped policy through arguments about the value of commodified health information. In addition, Ronald carried out participant observation (i.e., observing interactions between participants and attendees and posing questions) at two meetings – one public and one industry-sponsored. Finally, interviews were conducted with 17 participants involved in DTCA policymaking, including FDA officials and representatives of industry, consumer groups, and think tanks.

Fisher's research on the clinical trials industry consisted of 12 months of fieldwork in the southwestern US from 2003 to 2004. This qualitative research included 63 interviews and observation at over 20 for-profit research organizations in two major cities. Semi-structured interviews were clustered to get the perspective of multiple employees at individual investigative sites, including physicians, research staff, site administrators, and human subjects. Investigative sites were chosen to create a diverse sample of organizational forms: private practices, dedicated research sites, site management organizations, contract research organizations, and large (non-academic) hospitals. The sample also included interviews at two not-for-profit investigative sites. Additionally, Fisher attended industry conferences, joined industry professional organizations, and subscribed to industry publications. The purpose of the study was to investigate the relations, structures, and logics produced through the privatization of clinical trials.

MEDICAL NEOLIBERALISM IN DIRECT-TO-CONSUMER ADVERTISING (DTCA)

The pharmaceutical industry insists that DTCA can and should be thought of as a means to empower patients. It argues that advertisements educate the

public about diseases and the novel therapies that are available to treat them. The industry claims that millions of Americans would benefit from being aware of the latest treatment for depression or insomnia, for example, not only because of the product itself but also because it would encourage them to visit their doctors to seek a diagnosis. In short, the pharmaceutical industry frames DTCA and the information it provides to consumers as a solution to major public health problems, including the underdiagnosis and undertreatment of illnesses (Hogle, 2002).

While it may be no particular surprise that the pharmaceutical industry has mobilized consumer empowerment rhetoric for its own benefit, what is remarkable is the extent to which the US FDA seemingly accepted the argument that DTCA is empowering, propagated it within hearings, and used it to justify looser regulatory guidelines. This section explores the way empowerment rhetoric has dominated DTCA policy discourse. It then shows how what is labeled as empowering can be better thought of as a neoliberal maneuver to make individuals increasingly responsible for their health and well-being through the consumption of pharmaceutical products.

The Empowered Consumer in DTCA Policy Discourse

We saw that direct-to-consumer ads helped patients feel empowered so that they were better able to ask their doctor questions . . . that they were better able to take charge of their own health care. (Hausman, 2003, p. 232)²

Within policy discourse, proponents of DTCA justified its introduction by describing the emergence of a new healthcare subject, the *empowered consumer*. At DTCA meetings and hearings held in 1995, 1996, 2003, and 2005, a majority of participants claimed that DTCA would act in two ways: to turn passive individuals into empowered consumers and to help already-empowered consumers better manage their health (Division of Drug Marketing, Advertising, and Communications, 2006). Specifically, empowered consumers, according to the discourse, would ensure drug consumption by watching advertising, visiting their doctors, requesting prescriptions, and adhering to treatment regimens. DTCA discourse frames empowered consumers as aware, informed, and enlightened, as well as healthcare advocates, partners with doctors, and managers of their own health. Policy actors in favor of DTCA also include compliance as a key aspect of consumer empowerment (Calfee, Winston, & Stempski, 2002). This reveals a possible contradiction: consumers should be active enough to visit doctors

and request medications, but should not be so active that they decide not to consume those drugs.

Underlying these arguments about DTCA is the perspective that empowered consumers represent highly evolved patients. For example, an FDA official stated

The phenomenon of DTC advertising must be seen within the larger picture of the evolution of the patient's and consumer's role in their own health . . . It was not until the time of HIV and cancer activism in the late 1980s that the concept of patient empowerment really took hold. And I think it is no coincidence that around that time we began to see, again, reemergence in the interest . . . in direct-to-consumer advertising. (Woodcock, 2003, pp. 18–19)

Statements like these illustrate that FDA officials such as Janet Woodcock, then the director of the branch of the FDA responsible for regulating drug promotion, subscribed to the empowered consumer discourse. This evolutionary rhetoric implies that there is something both inevitable and progressive about the new kinds of consumers and drug promotion, while it simultaneously frames criticisms of DTCA as obstructions to progress.

DTCA discourse stresses the importance of empowered consumers by constructing at least two oppositions. First, empowered consumers are no longer in paternalistic doctor–patient relationships. Woodcock (2003) explained, “In the middle of the last century . . . [it] was viewed as proper that the patient might not know the name of their medication and that their prescriptions be written in a manner that they could not read. That was viewed as protective of the patient” (p. 18). Second, empowered consumers are not irrational mobs demanding prescriptions. Market researcher for *Prevention* magazine Ed Slaughter (2003) emphasized, “We don't have angry mobs of consumers with torches and pitchforks stampeding towards the doctor's office because they saw an ad on television or in a magazine” (p. 84). Setting up these two oppositions not only works to solidify the figure of the empowered consumer, but it also ridicules critiques that DTCA may lead to inappropriate prescribing. Patients as empowered consumers are reasoned, rational subjects who have access to the right information to get the medications they need.

The empowered consumer figure plays a strategic role within DTCA discourse, framing the policy problem as inadequate access to information that would enable drug use. Any risks associated with drug advertising and use are displaced by an emphasis on underdiagnosis, undertreatment, and noncompliance as more critical healthcare problems. For example, proponents of DTCA argue that advertising could help the 19 million

Americans with depression, most of whom are undiagnosed (American Advertising Federation, 2007). Furthermore, increased drug use will not only improve public health but also improve productivity by helping citizen-consumers to stay at work (Lichtenberg, 2003). In these various ways, policy actors consistently defined DTCA as information that empowers consumers and, in that context, opposition to DTCA came to sound like opposition to consumer empowerment.

Problems with the Empowered Consumer Discourse

The dominant actors in DTCA policy hearings strategically chose an appealing policy figure – the empowered consumer. Unlike HIV/AIDS activists who worked together to change medical and regulatory practices (Epstein, 1996; Chambré, 2006), these “empowered consumers” act as individuals who consume commodified information and healthcare, especially blockbuster drugs. The dominant policy actors expect consumers neither to question authority nor to change medical practice, but simply to request information and prescriptions from their doctors (which does happen, according to Iizuka & Jin, 2005). In other words, policy actors co-opted the rhetoric of patient activism whilst defining empowerment narrowly in terms of unquestioning individual consumption.

Although individuals have little power to enact change in healthcare governance overall (compared with collective action of social movements), truly informed patients may indeed be able to better manage their health. Unfortunately, prescription drug advertisements provide incomplete information for patients to make well-informed decisions about their own health. As a result of the 1997 FDA guidance, television and radio advertising need only state a handful of side effects and point viewers to print advertising elsewhere for fuller disclosure of risks. Studies have shown that risk information is “functionally absent” from advertisements, which are aimed at making the specific prescription drugs appeal to viewers (Day, 2005; Kalsher, 2006). In addition, a handful of prescription drugs dominate the mass media, while others go unadvertised. In 2005, the 20 most advertised prescription drugs accounted for more than 50% of all DTCA spending (General Accounting Office, 2006). Likewise, in the first half of 2007, only 15 drugs accounted for half of all spending (Mack, 2007). The high cost of advertising creates a bias towards new, expensive blockbuster medicines, rather than older drugs, generics, or even alternative treatments

(Avorn, 2003). Information from DTCA alone cannot therefore properly inform patients about the range of treatment options available to them.

Furthermore, describing healthcare subjects as “consumers” assumes that healthcare acts as a marketplace in which individuals make choices among products. Healthcare is far from an ideal marketplace, however, as patients are neither the sole decision-makers, nor usually the direct purchasers of the product. Moreover, autonomous decision-making is a role that many patients may be either unsuited to or unwilling to take on (Henwood, Wyatt, Hart, & Smith, 2003; Sulik and Eich-Krohm, this volume) and is further constrained by the vagaries of insurance plan reimbursement. By portraying patients as consumers in search of the best pill, “consumer choice” downplays the serious nature of illness as well as important safety concerns about pharmaceuticals.

DTCA policy discourse constructs the figure of an empowered consumer to define healthcare problems in terms of too little drug use and the solution as DTCA, which would catalyze individuals to consume medications. Empowerment is narrowly conceived in DTCA policy hearings in terms of advertisements prompting patient-consumers to visit doctors and request medications. By encouraging consumer advertising in 1997, the FDA did not so much empower consumers as turn patients, like doctors, into targets of pharmaceutical promotion. Patients are expected to govern their own health in this version of medical neoliberalism wherein proper governance means consumption of the latest blockbuster drug.

MEDICAL NEOLIBERALISM IN CLINICAL TRIALS

As with DTCA, pharmaceutical clinical trials are framed within a discourse of human subject empowerment. This section illustrates how research staff, such as physician investigators and study coordinators who conduct pharmaceutical industry studies, mobilize messages about empowerment during recruitment of subjects. It also shows a slippage between how research staff describe the empowerment of subjects and neoliberal discourses about responsabilization, wherein responsibility for the studies’ success or failure is shifted to subjects. In other words, while the goal of empowering human subjects may be admirable, the subtext within the clinical trials industry is to benefit the broader economic goals of pharmaceutical product development.

Subjects participate in clinical trials for myriad reasons, but several factors are common motivations: source of income, access to healthcare,

hope for a “magic bullet,” and desire to please physicians. The pharmaceutical industry relies heavily on impoverished and uninsured populations in the United States to become human subjects (Kolata & Eichenwald, 1999; Fisher, 2008). For healthy subjects, clinical trials provide an unparalleled source of income because many studies pay well over \$3,000 in exchange for participation. For others, especially patients without health insurance, pharmaceutical clinical trials offer “free” access to physicians and research staff, to diagnostic tests and services, and often to investigational drugs (others only receive placebos). The majority of pharmaceutical studies are double-blind placebo-control trials, meaning that subjects are randomized to treatment and placebo arms of the study but they – as well as the research staff – do not know who is receiving the investigational product. Placebos are widely used in pharmaceutical clinical trials because the majority of products being tested are for non-life-threatening diseases or illnesses. It is far easier for the pharmaceutical companies to show that their products are efficacious in trials comparing them to a placebo (that is, no treatment) than to a product already available on the market.

Although the practice of including disenfranchised groups could – and perhaps should – be perceived as ethically questionable or exploitative, the companies that are involved in clinical trials, particularly the sites conducting studies, instead frame their activities in terms of the service they provide to people who are in need of financial or healthcare resources. What is left unexamined is that patients in clinical trials do not receive individualized treatments for their illnesses, but they are the vehicles for testing the efficacy and safety of new drugs for the benefit of those who can afford them once they become available in the market. Because clinical trials seem like the only viable option for many people given the structural conditions motivating them to participate, they want to benefit personally from the studies (Fisher, 2008). Research staff use a discourse of empowerment to shift expectations regarding benefits that subjects can receive from studies, regardless of the effects of the investigational products or placebos on their bodies.

The Empowered Subject in Clinical Trials Industry Discourse

Research staff consider study participation empowering because human subjects are supposed to take on a more structured and active role in clinical trials than they do in standard medical care. For example, the process of

informed consent to participate in drug studies is designed to engage potential subjects in formal decision-making during which they are supposed to consider the benefits and risks of enrolling (Appelbaum, 1996). A research coordinator explained her role in that process, "It falls down to educating and *empowering* someone to make a good informed decision." Yet, it is the responsibility of research staff to empower subjects, rather than subjects empowering themselves, because few subjects express interest in the content of informed consent forms (Zussman, 1997; Corrigan, 2003; Fisher, 2006). This is because many have already decided to participate in studies before they ever receive the forms (Siminoff, Caputo, & Burant, 2004).

Moreover, patients' involvement with their medical treatments is perceived as relatively passive compared to study participation. Patients must simply be compliant with the treatment regimen created by their providers. In this view, physicians, as well as the products they prescribe to patients, perform the work to ameliorate illness. According to research staff, clinical trial participation, conversely, requires a different orientation between subjects, providers, and the pharmaceuticals they take as part of studies. As a coordinator explained, "It's just important that people don't think that 'Okay, I'm going to volunteer for a clinical trial, and everything is out of my hands and I don't know anything.' I mean, that's kind of the way it is in private practice ... *Not* in clinical research." The difference is that subjects, unlike patients, produce data about the products they consume as part of studies.

In order to make those data as robust as possible for the pharmaceutical companies, subjects must be active participants. In part, this means being compliant with all formal data collection measures. For example, many clinical trials require that subjects agree to attend frequent study visits in the clinic and/or to complete daily diaries tracking their symptoms. It also means that subjects need to be much more reflective and aware of the effects of the investigational products on their bodies. As a coordinator explained, "They know their own bodies, so they need to know that if they're taking this drug and something strange feeling or strange thing happens, they need to write those things down."

Research staff emphasize that it is empowering for subjects to be active study participants through their compliance with protocols and engagement with the effects of the drugs on their bodies. One coordinator said

I really impress upon them from the very beginning: "Your feedback, your documentation, your response is all that we have to give to the FDA for approval."

This is again [part of] the education and the empowering [of subjects]. Okay, it's not just I'm going down there and letting them draw blood out of my arm and getting a swab with the pap smear. [I tell them.] "The information from you, *your* perception of all of this, whether it's pain level whatever, is *critically* important to whether or not a medication or device is approved."

While individual human subjects may indeed feel empowered by their experiences in clinical trials, this is not the only outcome gained by encouraging subjects to be active participants.

Problems with the Empowered Subject Discourse

Regardless of the extent to which subjects are actively engaged in studies, the benefits of such "empowerment" are rather specious for subjects themselves. Ultimately, their compliance and reporting of symptoms are less in their interest than in the interest of pharmaceutical companies, on one hand, and public safety, on the other. Thus, instead of understanding subjects' participation in clinical trials through the lens of empowerment, it can be seen as evidence of responsabilization that accompanies neoliberal trends in healthcare (Rose, 1999).

Part of the thrust of research staff's discourse about subjects' participation is the point that subjects have rights granted by federal regulation but they also have responsibilities to pharmaceutical companies. In other words, instrumental reasons for participating are acceptable for the *initial* decision to enroll in studies, but subjects cannot seek only personal benefit, given the nature of clinical research. For example, a coordinator said, "You have to enroll patients who can understand *their* commitment toward the clinical trial that they're participating in . . . [I say,] 'Let me tell you what we need from you. This is *your* responsibility in this clinical trial: being there for these visits, documenting your diaries whether it's electronic or paper or whatever.'" Because the goal of studies is not to treat individual patients but to test the efficacy and safety of new products, subjects are told that they must commit to the data they help to produce rather than expect individual benefit. This is not to say that all subjects accept that the data must come before their own health, but the task for research staff, especially coordinators, is to impress upon subjects the importance of their participation in these terms.

As is the case in healthcare more generally, human subjects are cast as neoliberal consumers who make choices about their health for which they are responsible for the outcomes. The difference, however, between standard

medical care and pharmaceutical research is that subjects have fewer options and less control within the context of a study than do patients within the context of treatment. Subjects are presented simply with the decision to participate in studies, not to shape the details of their involvement. Nonetheless, they are responsible for tolerating any side effects, taking placebos, and completing all study logistics, such as appointments and study diaries. The goal of the neoliberal framing of personal responsibility is for subjects to internalize a new (learned) subjectivity toward clinical trials and to accept the goals of the research in spite of instrumental motivations they have to improve their own health or make money. As good neoliberal subjects, they are told to *choose* to remain in these studies not for themselves, but for the “advancement of science” and the profit of the pharmaceutical industry.

CONCLUSION

This chapter has examined the figure of the empowered consumer in neoliberal discourse about two aspects of pharmaceutical governance: DTCA policy and clinical trials practice. We have shown how empowerment rhetoric appropriates activist discourse to further industry goals. Individuals are expected to actively consume medication either through self-diagnosis and requesting prescriptions (DTCA) or through self-surveillance as research subjects (clinical trials practice).

On one hand, DTCA treats pharmaceuticals as consumer products, glorifying convenience and novelty, creating brands and brand loyalty of blockbuster drugs, and commodifying the conditions they treat. DTCA aims to persuade viewers that they suffer from conditions that can be treated with convenient new pills. DTCA thus intensifies the commodification of health by encouraging drug consumption and also by incentivizing the development of expensive new products that offer little, if any, clinical advantage over older treatments. As part of a neoliberal mode of pharmaceutical governance, DTCA enables the development of “me-too” drugs (Angell, 2004); the construction of new brands from old drugs (e.g., Sarafem, the rebranded Prozac) (Greenslit, 2005); and the marketing of a plethora of “lifestyle” drugs when major diseases across the globe go untreated (Shaffer & Brenner, 2004).

On the other hand, most clinical trials investigate relatively banal drugs, leading research subjects to give their bodies for the sake of consumer characteristics, like dosage. Approximately two-thirds of all new drug

applications made to the FDA are for products that are not significantly clinically different from drugs already on the market (Lee, 2006). In some cases, minor therapeutic advantages are coupled with major safety disadvantages (e.g., Vioxx and other cox-2 inhibitors) (Biddle, 2007). There is a disjunction, therefore, between the ideal of scientific research for the public good and the neoliberal governance of clinical trials wherein research facilities recruit impoverished, uninsured, or otherwise marginalized populations to investigate drugs that often represent little scientific and clinical advance. Moreover, these research agendas contribute to the further globalization of clinical trials as pharmaceutical companies seek disenfranchised populations around the world to test their products (Shah, 2006; Petryna, 2007).

Together, an examination of DTCA and clinical trials highlights the problematic nature of medical neoliberalism and the falsity of describing individuals within this system as “empowered.” The use of empowered consumer rhetoric is *strategic*: pharmaceutical industry actors and their allies require subjects to be empowered solely when it furthers the industry goal of increasing the production and consumption of blockbuster drugs.³ The notion that empowered consumers may choose *not* to consume is denied within the industry rhetoric of empowerment, especially when coupled with the language of compliance. Rather than making active decisions, compliant consumers must instead obey instructions and take medications in spite of any problems that arise.

Difficulties with medicine consumption – that neoliberal discourse largely ignores – include inherent hazards and inequitable access. Consumer empowerment rhetoric implies both that consumption is an overall good and that new pharmaceuticals represent scientific progress. In clinical trials practice, patients subject themselves to unknown hazards for the sake of relatively meaningless drugs. Once a drug is approved, DTCA broadens and hastens its use without adequate surveillance (Fontanarosa, Rennie, & DeAngelis, 2004).

Consumer empowerment rhetoric also obstructs questions of access. Framing healthcare as a marketplace wherein individuals are free to make consumer choices ignores the fact that US healthcare is a grossly inequitable system, with about 43 million Americans with no health insurance at all (Reuters, 2007). The neoliberal representation of the undertreatment of illness resulting from ignorant individuals is at best a distraction from these severe social and economic inequities. Pharmaceutical clinical trials take advantage of the current system by promising access to a version of healthcare. This limited access comes at an obvious price, with healthy or

uninsured people subjecting themselves to unknown risks for the sake of new drugs with little therapeutic advantage over older, cheaper products.

What Would Meaningful Empowerment Look Like?

This chapter has thus far demonstrated (1) the presence of a neoliberal discourse of empowered consumers in DTCA policy and clinical trials practice and (2) the unlikelihood of meaningful consumer empowerment in the current mode of pharmaceutical governance. Depending on their position within US society, some patients have the “choice” between no healthcare at all or the limited healthcare afforded to research subjects, while others – fortunate to have health insurance – choose among new pharmaceutical brands, with relatively unknown safety profiles. In both cases, patients help pharmaceutical companies expand their profit margins by consuming the latest blockbuster drug (e.g., sleeping pills, statins for cholesterol control, or SSRIs for depression or anxiety). Instead of asking first how best to inform and empower consumers, industry uses the notion of consumer empowerment post hoc to justify its predetermined goals. This section suggests several changes in pharmaceutical governance that would more truly empower patients and consumers.

DTCA policy discourse claims that advertising provides useful information that empowers health consumers. However, DTC advertisements provide incomplete and biased information, existing only for a narrow range of treatments and communicating risks ineffectively. Consumer empowerment can only arise via *complete* information of a wide range of treatment options produced by an independent source. Examples include online information produced by governmental organizations (e.g., National Library of Medicine) and independent consumer organizations (e.g., Consumers Union and Public Citizen). This kind of balanced information, however, cannot compete with television or magazine advertising unless they run alongside product advertising with equal media presence and advertising force. Independent advertising could be produced by the government⁴ – with input from a consortium of noncommercial consumer and professional groups – and could be both non-specific (about the unknown, substantial risks of new prescription drugs) and specific (outlining the variety of treatment options for particular conditions). The goal would be meaningful understanding of risks and benefits of all treatment options, and knowledge that the most practical option may be an older treatment with a well-understood safety profile.

In addition, while it is widely agreed that health movements have enabled patients to participate more fully in healthcare decisions, consumer empowerment may still require the safeguards built by strong doctor–patient relationships wherein patients use doctors’ advice to weigh their clinical options. Particularly valuable professional advice would come from doctors who are themselves relatively neutral. Currently, this is not the case as doctors regularly rely on pharmaceutical promotion for drug information and accept pharmaceutical industry gifts (Kassirer, 2005). State medical boards should draft specific, stringent guidelines to limit these relationships between physicians and the pharmaceutical industry and to enable unsponsored continuing medical education for balanced treatment information.

Improved pharmaceutical governance for truly empowered consumers also requires thorough postmarketing reporting. For example, although Vioxx was responsible for an estimated 27,000 deaths or heart attacks, Merck delayed its withdrawal for four years, while heavily marketing the drug and receiving \$2.5 billion per year in sales (Berenson, Harris, Meier, & Pollack, 2004). Prescription drugs are responsible for 180,000 deaths in the United States each year (Strand, 2006). If data were gathered methodically after drugs are released to the general public, regulators would be able to provide fuller warnings and, where needed, remove drugs from the market promptly. In 2008, Consumers Union began a campaign to persuade Congress to require that all DTCA include the toll-free number for reporting adverse effects. Another mechanism to improve postmarketing reporting would be to mandate that pharmacists collect this information – and compensate them for doing so. Reporting should become so routine that it is done for every prescription drug. To facilitate this information exchange, pharmacists could include a drug use questionnaire with every prescription they dispense and should be routinely notified of deaths.

The problem remains, however, that most new drugs are relatively meaningless contributions to our pharmacopoeia, in terms of clinical advantages over existing medications, and thereby needlessly expose consumers to risk – whether through prescription use or as part of clinical trials. For example, the prescription drug Lamisil, widely advertised – and prescribed – for treating toenail fungus, comes with serious risks, including liver failure. One solution to this dilemma would be to shift pharmaceutical priorities by mandating that clinical trials compare new drugs to *existing drugs*, using the standard of care and comparable dosages (Angell, 2004). The burden on pharmaceutical companies should not merely be to prove

that new products are better than a sugar pill but that they add to treatment options in a clinically meaningful way.

These four changes to pharmaceutical governance – complete, unbiased information provision, limitations on financial arrangements between doctors and the pharmaceutical industry, adequate postmarketing reporting, and more meaningful clinical trials – would help safeguard patients against the problems generated by neoliberal pharmaceutical governance. Such changes might prompt the pharmaceutical industry to reprioritize drug development and to put into practice its own rhetoric about its mission of improving health and curing diseases. By modifying the ways in which pharmaceutical companies could gain profits from their products, power relations between the industry and consumers – patients as well as providers – could be made more equitable.

Nonetheless, useful and safe drugs are only one part of the necessary shift. For meaningful empowerment to occur, the current coercive structures of US healthcare would have to be altered, such that individuals could make a wider range of decisions about their health and well-being. The current model of consuming prescription medications, including participating in pharmaceutical clinical trials, is too limiting to allow for much patient empowerment. For example, subjects should not be in the position that the only way to access any healthcare is to “choose” to be research subjects. Without health insurance for all Americans, consumer empowerment will remain a powerful myth that perpetuates health inequalities.

NOTES

1. There is a well-documented history of the clinical development of AIDS drugs (Chambré, 2006; Epstein, 1996) and cancer therapies (Hess, 1997), but those cases do not generalize well to the development of other pharmaceutical products. There are several important differences. First, HIV/AIDS and cancer are life-threatening illnesses; the majority of products currently being developed by pharmaceutical companies are for illnesses that can already be managed by other products and therapies available on the market. Second, HIV/AIDS and cancer are unique illnesses in that there are well-organized patient advocacy and activist groups supporting research activities. Third, the bulk of research support for HIV/AIDS (76%) and cancer (67%) is generated by the public sector, particularly the National Institutes of Health, and these diseases represent only a fraction of the pharmaceutical industry's research and development (R&D) investment. Roughly only 12% and 22% of industry R&D each year is spent on developing products targeting treatments or cures for infectious disease (including HIV/AIDS) and cancer respectively (CenterWatch, 2006).

2. Angela Hausman, a marketing professor, has recently carried out research on the effects of attitude towards DTCA on prescription drug requests (Hausman, 2008). It is worth noting that most empirical research on DTCA examines consumer attitudes to DTCA in general rather than consumer behavior or health effects. A notable exception showed how advertisements for HIV/AIDS treatments downplayed the severity of the condition such that they prompted viewers to engage in risky sexual behavior (Klausner, Kim, & Kent, 2002).

3. See Bourgeault et al. (this volume) on the strategic use of consumer choice rhetoric by obstetricians to justify the high rate of cesarean births in the United States and United Kingdom.

4. In a recent case, the Supreme Court determined that federally mandated beef promotion did not violate the First Amendment because it was government speech (*Johanns v. Livestock Marketing Association*, 2005). This opens up the possibility for the government to create its own prescription drug campaigns.

REFERENCES

- American Advertising Federation. (2007). Letter to Senate Committee on Health, Education, Labor and Pensions, January 30. Retrieved on 13 July 2007. Available at http://www.aaf.org/government/pdf/tac_kennedy012907.doc
- Angell, M. (2004). *The truth about the drug companies: How they deceive us and what to do about it*. New York, NY: Random House.
- Appelbaum, P. S. (1996). Commentary: Examining the ethics of human subjects research. *Kennedy Institute of Ethics Journal*, 6(3), 283–287.
- Arnold, M. (2005). Changing channels. *Medical Marketing and Media*, 40(4), 34–39. Retrieved May 21, 2006, from <http://offlinehbpl.hbpl.co.uk/Misc/MMM/Features/APR05%2034-42%20DTC%20OUTLOOK.pdf>
- Associated Press. (2008). Companies pull TV ads for Vytorin. King5.com, January 24. Available at http://hosted.ap.org/dynamic/stories/V/VYTORIN_ADS
- Avorn, J. (2003). Advertising and prescription drugs: Promotion, education, and the public's health. *Health Affairs*, W3, 104–108.
- Becker, D. (2005). *The myth of empowerment: Women and the therapeutic culture in America*. New York, NY: New York University Press.
- Berenson, A., Harris, G., Meier, B., & Pollack, A. (2004). Dangerous data: Despite warnings, drug giant took long path to Vioxx recall. *New York Times* online, November 14. Available at <http://www.nytimes.com/2004/11/14/business/14merck.html>
- Biddle, J. (2007). Lessons from the Vioxx debacle: What the privatization of science can teach us about social epistemology. *Social Epistemology*, 21(1), 21–39.
- Biven, W. C. (2001). *Jimmy Carter's economy: Policy in an age of limits*. Chapel Hill, NC: The University of North Carolina Press.
- Bodenheimer, T. (2000). Uneasy alliance: Clinical investigators and the pharmaceutical industry. *New England Journal of Medicine*, 342(20), 1539–1544.
- Boehm, D. A. (2005). The safety net of the safety net: How federally qualified health centers 'subsidize' Medicaid managed care. *Medical Anthropology Quarterly*, 19(1), 47–63.

- Calfee, J. E., Winston, C., & Stempski, R. (2002). Direct-to-consumer advertising and the demand for cholesterol-reducing drugs. *The Journal of Law and Economics*, 45, 673–690.
- CenterWatch. (2006). *2006 state of the clinical trials industry*. Boston, MA: Thomson CenterWatch.
- Chambré, S. M. (2006). *Fighting for our lives: New York's AIDS community and the politics of disease*. New Brunswick, NJ: Rutgers University Press.
- Cohen, L. (2003). *A consumers' republic: The politics of mass consumption*. New York, NY: Alfred Knopf.
- Corrigan, O. P. (2003). Empty ethics: The problem with informed consent. *Sociology of Health and Illness*, 25, 768–792.
- Darvall, L. (1993). *Medicine, law and social change: The impact of bioethics, feminism and rights movements on medical decision-making*. Brookfield: Dartmouth Publishing Group.
- Day, R. (2005). Comprehension of benefits versus risks: Is there fair balance? *Public hearing on direct-to-consumer promotion of medical products*, November 1. Retrieved on July 13, 2007. Available at <http://www.fda.gov/cder/ddmac/dtc2005/default.htm>
- Division of Drug Marketing, Advertising, and Communications. (2006). *Meetings*. Retrieved on 13 July 2007. Available at <http://www.fda.gov/cder/ddmac/meetings.htm>
- Elliott, C. (2003). *Better than well: American medicine meets the American dream*. New York, NY: W.W. Norton.
- Epstein, S. (1996). *Impure science: AIDS, activism, and the politics of knowledge*. Berkeley, CA: University of California Press.
- Fisher, J. A. (2006). Procedural misconceptions and informed consent: Insights from empirical research on the clinical trials industry. *Kennedy Institute of Ethics Journal*, 16(3), 251–268.
- Fisher, J. A. (2007). 'Ready-to-Recruit' or 'Ready-to-Consent' populations? Informed consent and the limits of subject autonomy. *Qualitative Inquiry*, 13(6), 875–894.
- Fisher, J. A. (2008). *Medical research for hire: The political economy of pharmaceutical clinical trials*. New Brunswick, NJ: Rutgers University Press.
- Fontanarosa, P. B., Rennie, D., & DeAngelis, C. D. (2004). Postmarketing surveillance: Lack of vigilance, lack of trust. *Journal of the American Medical Association*, 292, 2647–2650.
- Frank, A. W. (2002). What's wrong with medical consumerism?. In: S. Henderson & A. Petersen (Eds), *Consuming health: The commodification of health care* (pp. 13–30). New York, NY: Routledge.
- General Accounting Office. (2006). Prescription drugs: Improvements needed in FDA's oversight of direct-to-consumer advertising [GAO-07-54]. Available at <http://www.gao.gov/htext/d0754.html>
- Gilliom, J. (2001). *Overseers of the poor: Surveillance, resistance, and the limits of privacy*. Chicago, IL: University of Chicago Press.
- Giroux, H. A. (2004). *The terror of neoliberalism: Authoritarianism and the eclipse of democracy*. Boulder, CO: Paradigm Publishers.
- Grace, V. M. (1991). The marketing of empowerment and the construction of the health consumer: A critique of health promotion. *International Journal of Health Services*, 21(2), 329–343.

- Greenslit, N. (2005). Depression and consumption: Psychopharmaceuticals, branding, and new identity practices. *Culture, Medicine, and Psychiatry*, 29, 477–501.
- Guidance for Industry on Consumer-Directed Broadcast Advertisements, 64 Fed. Reg. 43197. (1999).
- Harvey, D. (2005). *A brief history of neoliberalism*. New York, NY: Oxford University Press.
- Hausman, A. (2008). Direct-to-consumer advertising and its effect on patient requests. *Journal of Advertising Research*, 2, 42–56.
- Hausman, A. V. (2003). DTC advertising and its impact on patient healthcare behaviors, in Food and Drug Administration, *Direct-to-consumer promotion: Public meeting*, September 22. Retrieved on 13 July 2007. Available at www.fda.gov/cder/ddmac/DTCmeetingTranscript.doc
- Henwood, F., Wyatt, S., Hart, A., & Smith, J. (2003). 'Ignorance is bliss sometimes': Constraints on the emergence of the 'informed patient' in the changing landscapes of health information. *Sociology of Health and Illness*, 25(6), 589–607.
- Hess, D. J. (1997). *Can bacteria cause cancer? Alternative medicine confronts big science*. New York, NY: New York University Press.
- Hogle, L. F. (2002). Claims and disclaimers: Whose expertise counts? *Medical Anthropology*, 21, 275–306.
- Iizuka, T., & Jin, T. Z. (2005). The effect of prescription drug advertising on doctor visits. *Journal of Economics and Management Strategy*, 14(3), 701–727.
- Johanns v. Livestock Marketing Association, 544 U. S. 550. (2005).
- Kalsher, M. (2006). Influence of presentation modality on communication of pharmaceutical risk information in direct-to-consumer (DTC) television commercials. Paper presented at 16th World Congress in Ergonomics, Maastricht, The Netherlands.
- Kassirer, J. P. (2005). *On the take: How America's complicity with big business can endanger your health*. New York, NY: Oxford University Press.
- Klausner, J. D., Kim, A., & Kent, C. (2002). Are HIV drug advertisements contributing to increases in risk behavior among men in San Francisco, 2001? *AIDS*, 16, 15–16.
- Kolata, G., & Eichenwald, K. (1999). Stopgap medicine: For the uninsured, experiments may provide the only treatment. *New York Times*, June 22.
- Lee, C. (2006). New drugs declining, research costs increasing, GAO says. *Washington Post*, December 20, p. A08.
- Lichtenberg, F. R. (2003). DTC advertising and public health, in Food and Drug Administration, *Direct-to-consumer promotion: Public meeting*, September 23. Retrieved on July 13, 2007. Available at www.fda.gov/cder/ddmac/DTCmeetingTranscript2.doc
- Mack, J. (2007). Lunesta's Ad spending spree and other DTC oddities. Pharma marketing blog, December 13. Retrieved on January 26, 2008. Available at <http://pharmamktng.blogspot.com/2007/12/lunestas-ad-spending-spreed-and-other.html>
- Monahan, T. (2005). *Globalization, technological change, and public education*. New York, NY: Routledge.
- Monahan, T., & Wall, T. (2007). Somatic surveillance: Corporeal control through information networks. *Surveillance and Society*, 4(3), 154–173.
- Morgen, S. (2002). *Into our own hands: The women's health movement in the United States, 1969–1990*. New Brunswick, NJ: Rutgers University Press.

- Nichter, M., & Nichter, M. (1996). *Anthropology and international health: Asian case studies*. Amsterdam, NL: Gordon and Breach.
- Niggle, C. (2003). Globalization, neoliberalism and the attack on social security. *Review of Social Economy*, 61(1), 51–71.
- Petryna, A. (2007). Clinical trials offshored: On private sector science and public health. *BioSocieties*, 2(1), 21–40.
- Petryna, A., Lakoff, A., & Kleinman, A. (Eds). (2006). *Global pharmaceuticals: Ethics, markets, practices*. Durham, NC: Duke University Press.
- Pierson, P. (1994). *Dismantling the welfare state? Reagan, Thatcher, and the politics of retrenchment*. Cambridge, UK: Cambridge University Press.
- Pines, W. L. (1999). A history and perspective on direct-to-consumer promotion. *Food and Drug Law Journal*, 54, 489–518.
- Reuters. (2007). Survey finds 43.6 million uninsured in U.S. *New York Times*, June 26. Retrieved on 13 July 2007. Available at <http://www.nytimes.com/2007/06/26/washington/26insure.html>
- Ronald, L. M. (2006). *Empowered to consume: Direct-to-consumer advertising and pharmaceutical governance*. Troy, NY: Rensselaer Polytechnic Institute.
- Rose, N. (1999). *Powers of freedom: Reframing political thought*. New York, NY: Cambridge University Press.
- Schram, S. F. (2006). *Welfare discipline: Discourse, governance and globalization*. Philadelphia, PA: Temple University Press.
- Scott, W. R., Caronna, C. A., Ruef, M., & Mendel, P. J. (2000). *Institutional change and healthcare organizations: From professional dominance to managed care*. Chicago, IL: University of Chicago Press.
- Shaffer, E., & Brenner, J. (2004). Trade and healthcare: Corporatizing vital human services. In: M. Fort, M. A. Mercer & O. Gish (Eds), *Sickness and wealth: The corporate assault on global health*. Cambridge, MA: South End Press.
- Shah, S. (2006). *The body hunters: How the drug industry tests its products on the world's poorest patients*. New York, NY: The New Press.
- Siminoff, L. A., Caputo, M., & Burant, C. (2004). The promise of empirical research in the study of informed consent theory and practice. *HEC Forum*, 16(1), 53–71.
- Slaughter, E. (2003). *Direct-to-consumer promotion: Public meeting*, September 22. Retrieved on 13 July 2007, from Food and Drug Administration www.fda.gov/cder/ddmac/DTCmeetingTranscript.doc
- Starr, P. (1982). *The social transformation of American medicine: The rise of a sovereign profession and the making of a vast industry*. New York, NY: Basic Books.
- Strand, R. D. (2006). *Death by prescription: The shocking truth behind an overmedicated nation*. Nashville, TN: Thomas Nelson.
- Talbot, M. M. (2000). Strange bedfellows: Feminism in advertising. In: M. Andrews & M. M. Talbot (Eds), *All the world and her husband: Women in twentieth-century consumer culture* (pp. 177–191). London, UK: Cassell.
- Thomas, J. E., & Zimmerman, M. K. (2007). Feminism and profit in American hospitals: The corporate construction of women's health centers. *Gender and Society*, 21, 359–383.
- Timmermans, S., & Berg, M. (2003). *The gold standard: The challenge of evidence-based medicine and standardization in health care*. Philadelphia, PA: Temple University Press.

- van der Geest, S., Whyte, S. R., & Hardon, A. (1996). The anthropology of pharmaceuticals: A biographical approach. *Annual Review of Anthropology*, 25, 153–178.
- Washington Legal Foundation v. Friedman, 13 F. Supp. 2d 51. (1998).
- Woodcock, J. (2003). *Direct-to-consumer promotion: Public meeting*, September 22. Retrieved on 13 July 2007, from Food and Drug Administration www.fda.gov/cder/ddmac/DTCmeetingTranscript.doc
- Zussman, R. (1997). Sociological perspectives on medical ethics and decision-making. *Annual Review of Sociology*, 23, 171–189.

(C) Emerald Group Publishing Limited