Partial Progress: Governing the Pharmaceutical Industry and the NHS, 1948–2008

John Abraham
University of Sussex

Abstract Coinciding with sixty years of the U.K. National Health Service (NHS), this article reviews the neglected area of the governance of the pharmaceutical industry and the NHS. It traces the relationships between the pharmaceutical industry, the state, and the NHS from the creation of the health service to the present, as they have grappled with the overlapping challenges of pharmaceutical safety, efficacy, cost-effectiveness, pricing, promotion, and advertising. The article draws on the concepts of "corporate bias" and "regulatory capture" from political theory, and "countervailing powers" and "clinical autonomy" in medical sociology, while also introducing the new concepts of "assimilated allies" and "pharmaceuticalization" in order to synthesize a theoretical framework capable of longitudinal empirical analysis of pharmaceutical governance. The analysis identifies areas in which the governance of pharmaceuticals and the NHS has contributed to progress in health care since 1948. However, it is argued that that progress has been slow, restricted, and vulnerable to misdirection due to the enormous and unrivaled influence afforded to the pharmaceutical industry in policy developments. Countervailing influences against such corporate bias have often been limited and subject to destabilization by the industry's assimilated allies either within the state or in the embrace of pharmaceuticalization and consumerism.

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Introduction

The U.K. National Health Service (NHS) had its sixtieth birthday on July 5, 2008. It was a flagship of British health policy in the postwar period and remains at the heart of health care in the United Kingdom. Moreover, for many years it has been internationally renowned by many as one of the major models of health care provision for emulation around the world. Even in the United States, where the dominant culture has been suspicious of the collectivist political principles upon which the NHS was founded, several U.S. administrations have been impressed by its provisions of universal access and comprehensive coverage (Navarro 1994). While U.S. politicians have not adopted the NHS model, some have sought and continue to seek a model that broadens access and coverage, as the apparent deficits of the U.S. health system compared with the NHS in these respects become more familiar to American citizens.

Not surprisingly, therefore, there have been thousands of publications about the NHS. Many authors have examined the political and health care implications of the "modernization," "privatization," and "managerial" policies of the NHS since the early 1980s, often by comparison with the service's early ideals (Giaimo 2002; Greer 2004; Hardy 2001; Klein 2006; Pollock 2004; Rivett 1998; Webster 1998). Indeed, Fox (2004) has shown how those early ideals were attenuated by a U.S. government pressing for "anti-Soviet" military expenditure over spending on health within the Marshall Plan for Britain of the late 1940s and early 1950s. However, social science or academic policy publications about the governance of the NHS and the pharmaceutical industry over a longitudinal period of time are extremely rare. The expanding field of research on the regulation and audit of health care quality in the NHS has made little more than passing reference to pharmaceuticals (Black 1997; Brennan 1998; Tuohy 2003; McGuire 2005). There is also a growing literature about evidence-based and cost-containment approaches to management, "competition," and policy in the NHS, which occasionally refers to rationalization of pharmaceutical provision but generally without locating it in the context of the overall governance of the pharmaceutical industry (Abel-Smith 1985; Drummond, Cooke, and Walley 1997; Hassel et al. 2003; Light 2001; Mold and Berridge 2007; Ovretveit 1993; Walshe and Rundall 2001).

In this article, I trace the relationships between the pharmaceutical industry, the state, and the NHS from the creation of the health service to the present, as the players have grappled with the overlapping chal-

lenges of five key aspects of pharmaceutical governance: safety, efficacy, cost-effectiveness, pricing, and promotion and advertising. The purpose of the article is not only to address an area of neglect in social science and health policy analysis but also to provide insights into some of the political dynamics and limitations that have been central to the management of pharmaceuticals in one of the world's most renowned modern health systems. In 2009, the NHS faces many problematic choices and opportunities in pharmaceutical policy, so it is timely and instructive to reflect on how such policy has developed, changed, and maintained itself over time.

To understand the governance of the pharmaceutical industry and the NHS in this sixty-year period, I synthesize an approach drawing on medical sociology and political theory. In particular, I modify and extend Light's (1995) "countervailing powers" framework for analyzing health professions and the state in combination with Middlemas's (1979) notion of "corporate bias" as an articulation of the relationship between the state and organized interests in Britain. Both these theoretical conceptions relate to longitudinal institutional analysis, so they are highly appropriate for an investigation of the governance of the pharmaceutical industry and the NHS over the last sixty years. Specifically, Light's framework suggests that the power of health professions varies over time in relation to the state, and that the establishment and maintenance of power by a particular profession at a moment in history is dependent on its capacity to overcome countervailing powers from within other professional groups or the state. Relatedly, Middlemas explains how an organized interest (the British trade unions) can attain considerable influence on governance by continual privileged access to the state—a corporate bias that helps that organized interest to be shielded from challenges to its policy objectives by countervailing powers. Modifying beyond this conceptual framework, I suggest that to fully comprehend variations in the power and influence of an organized interest over time, one must not only take account of countervailing powers but also consider what I call "assimilated allies" who may reinforce, rather than counteract, corporate bias.

In this article, I apply this extended synthesis to the pharmaceutical industry as an organized interest. I argue that the governance of the NHS regarding pharmaceuticals has been shaped by a corporate bias favoring the research-based manufacturing industry. However, the extent of that corporate bias has varied not merely over the time dimension (as Light's framework would suggest) but also regarding the particular aspect of governance involved and according to both countervailing powers and assimilated allies. I also draw on the concept from political science known as

"regulatory capture," a variable and dynamic effect of corporate bias that describes a shift in policy by government agencies away from regulation in the interests of patients and public health to prioritization of the private interests of the regulatees instead. The sociological concepts of "clinical autonomy" (i.e., doctors' freedom to prescribe whatever drugs they see fit for any individual patient) and "consumerism" (i.e., increased patient awareness, reflexivity, and individualized/organized demand for access to apparently promising drug treatments) are also needed to explain the architecture of the medical profession and NHS patients' "demands" as potential assimilated allies or countervailing powers to the pharmaceutical industry's stake in corporate bias. In addition, I introduce the new concept of "pharmaceuticalization" (the process by which social, behavioral, or bodily conditions are treated, or deemed to be in need of treatment, with medical drugs by doctors or patients) as a mechanism that affords the industry extensive opportunities for the simultaneous creation of assimilated allies and deflection of countervailing powers.

In broad historical terms, I demonstrate that some of the key policy issues regarding pharmaceuticals in the NHS became evident very soon after the NHS was first established and have recurred, while others emerged due to the nonviability of initial governance arrangements. The key substantive empirical arguments, which will be developed in detail later in the article, may be prefaced as follows.

Regarding the governance of drug safety, efficacy, and pricing, I contend that a corporate bias has been unmistakably dominant, permitting the industry from the outset to have privileged access to and influence over the British state, access not afforded to any other interest group. The industry and the state have recruited medical experts to serve their interests in safety and efficacy regulation, but it is the dominance of pharmaceutical industry interests and commercial power, often so coveted by the regulatory state and senior medical experts, that has commanded attention. With respect to the rationalization of NHS drug prescribing and cost-effectiveness regulation, the state has at times asserted its own interests, independent of and in conflict with the industry. While this positioned the state as a countervailing power against industry-dominated corporate bias, it also placed the state in opposition to the medical profession's concerns about "clinical autonomy." Such concerns have been salient in this context, sometimes yielding concessions from government that protect doctors' authority and discretion. Simultaneously, those concerns encouraged the industry to assimilate the medical profession as allies in the industry's quest to undermine those elements of the state having countervailing

effects on corporate bias. The power of the industry to use the courts, gain privileged access to government, and mobilize alliances of organized groups of patients and health professionals has arguably been more important than assertions of clinical autonomy in frustrating the state's rationalization objectives and in redirecting them in line with industry interests as a form of "regulatory capture."

Furthermore, government efforts to rationalize NHS drug use have expanded in a U.K. context of growing "pharmaceuticalization" and "consumerism." Pharmaceuticalization, encouraged by both the industry's promotion and advertising of its products and many medical professional associations, has expanded doctors' prescribing horizons within the NHS, often making difficult the distinction between rational prescribing based on collective health priorities and promotional claims for the therapeutic value of new products. This is further complicated by the "consumerist" policy discourse of "expert patients" and "informed patients" that has emerged since the late 1990s in the United Kingdom.[1] I argue that the establishment of this discourse, as if it were a reflection of "patient demand," has encouraged the misidentification of pharmaceuticalization as deprofessionalization in the NHS and tends to obscure the distinction between the strategies of industry/government to advance their interests, on the one hand, and the interests of patients and public health, on the other. Thus, the twin processes of pharmaceuticalization and consumerism have predominantly served to assimilate the potential countervailing powers of the medical profession, NHS, and patients into allies of corporate bias in governance.

A Nationalized Health Service and a Private Pharmaceutical Industry: The Early Postwar Period

With the introduction of the NHS in 1948, health care became nationalized and was placed predominantly in the public sector, but the pharmaceutical industry remained in the private sector. At the 1973 British Labour Party conference, Harold Wilson, the party leader, asserted that the case for partial public ownership of the pharmaceutical industry "needs no argument," and Labour entered the February 1974 general election with

1. The concept of "expert patient" probably dates back to the mid-1980s when it was used by the private health company Kaiser Permanente in U.S. discussions of patient self-care (Taylor and Bury 2007).

a manifesto proposing to take over sections of the industry (Association of the British Pharmaceutical Industry [ABPI] 1974a, 1974b). However, despite Wilson's winning the election, the pharmaceutical industry has, for better or worse, never been nationalized in any form in the United Kingdom. Many of the complex dynamics of the relationships between the pharmaceutical industry, the state, and the NHS stem from that initial decision to keep the industry in the private sector—for example, the fact that the NHS has to purchase its medicines from an industry that largely controls the direction of drug development and seeks maximization of prices and profits to meet its commercial objectives. Consequently, the state has had to become involved in the regulation, rather than direction, of the industry with respect to drug safety, efficacy, cost-effectiveness, profits, pricing, and advertising.

When the NHS was created, the modern pharmaceutical industry was well under way. Since the Industrial Revolution, pharmaceutical production had moved from apothecary shops to large-scale, scientific laboratories in major firms (Penn 1979). The "quality" of pharmaceuticals was regulated by the 1875 Sale of Food and Drugs Act (Hodges 1987). This outlawed drug adulteration, that is, "any procedure that produces an alteration in strength or purity, or both, from the avowed standard of a drug, whether through intent or neglect" (Stieb 1966: 129–130). Regulation of drugs' quality, however, implied nothing about their safety or efficacy; it helped only to ensure that the pharmaceutical product contained the ingredients claimed on the label. This was tragically demonstrated by the Elixir Sulfanilamide disaster in 1937 in the United States, where, as in the United Kingdom, drug quality, but neither safety nor efficacy, was regulated. The ingredients were of high "quality," but formed a toxic combination that killed 103 people, most of whom had taken it by prescription from their doctors (Temin 1980).

Before the NHS, access to health care and medical treatment was governed by the 1911 National Health Insurance (NHI) Act, under which only people on or below a low-income level could receive "medical benefit" via a national system of insurance funded by statutory contributions from the employer, the state, and the employed—of which the state paid less than a quarter (Bruce 1961). With the NHS, the benefits of free medical care were extended to the whole population and the government footed the bill. The number of prescriptions under the NHS in 1951 more than trebled to 220 million compared with the number given under the NHI Act, rising to 318 million in 1980 and 425 million in 1992 (House of Commons Health Committee [HCHC] 1994; Public Records Office [PRO] 1951). Moreover,

the introduction of potent prescription drugs like penicillin in the 1940s transformed the kinds of medicines produced by the industry (Mann 1984). Many companies sought to replicate those therapeutic breakthroughs, creating a plethora of equally powerful drugs. Industrial promotion of drugs to doctors intensified, with consequent increases in drug prescribing, while the large research-based firms used patents to command high monopoly prices for their drugs (Silverman and Lee 1974: 48–80).

Thus, very soon in the life of the NHS, the cost and relative value of drugs purchased by the service became a significant issue. In 1949, the Ministry of Health (MoH) established the Joint Committee on Prescribing (JCP) to consider restricting NHS doctors from prescribing "medicines of doubtful value" or "unnecessarily expensive brands of standard drugs" (Joint Committee on Prescribing 1950: 4). The ministry instigated a review of drug legislation which found that "a major cause of the proprietary [NHS] drug bill is the prescription of duplicate or doubtful medicines following skilful propaganda from the drug firms to the doctors in the service, and in some cases following advertising to the public which in turn results in pressure on the doctor by the patient" (PRO 1951). The review proposed a register of prescribable NHS drugs, excluding those which the JCP thought lacked efficacy (ibid.). Meanwhile, the MoH issued a circular asking doctors not to prescribe proprietary (i.e., brand-name) preparations unless "satisfied that a standard [generic] drug or combination of standard drugs cannot be prescribed with equal effect" (Pharmaceutical Society of Great Britain [PSGB] 1950a).

The Association of the British Pharmaceutical Industry (ABPI) was anxious about the ministry's plans to rationalize drug prescribing because the NHS was the industry's largest customer, and too much standardization of the home trade could damage the industry's export capabilities. As the president of the ABPI put it, "If the well-known branded names of preparations disappear they will no longer figure in the medical journals published here and be circulated widely overseas and this will make it more difficult for the export industry to develop" (PSGB 1950b). These were particularly influential arguments because recovery of the postwar U.K. economy was led by the export boom of the sectors that had done well during the war, including the pharmaceutical industry (Aldcroft 1986: 1–43). The ABPI appreciated this, astutely declaring that "the contribution of the industry should be taken as a whole—its help in reducing problems of the Chancellor of the Exchequer by maintaining the value of sterling abroad should be put alongside its ability to deliver the goods for our own Health Service" (PSGB 1956b).

In private meetings and correspondence with the MoH, the ABPI argued that it was undesirable for the JCP to publish a report which classified drugs therapeutically because such a list would be used to keep British products out of foreign markets (PRO 1950d, 1950c). The government's Board of Trade also joined the fray by pointing out in a letter to the MoH that almost one-third of brand name drugs were exported and that the annual rate of export was valued at £4.5 million. The letter continued, "There is a danger that certifying authorities or other import licensing authorities in other countries may gain access to the Ministry of Health list of 'banned' items and may refuse to grant authority to sell or import these proprietary medicines . . . Accordingly, I suggest that very great care should be taken to keep the list strictly confidential and, so far as possible, to avoid any undue publicity being given to the scheme as a whole" (PRO 1950a).

Despite these protests, the JCP lists were published, albeit discreetly, for, as the MoH noted, no cost-cutting benefit to the NHS could be derived from the reports if they were not circulated to doctors (PRO 1950b). However, corporate bias had been established. For the rest of the decade, the industry and its allies in the Board of Trade persuaded any countervailing powers at the MoH that the export trade of the pharmaceutical industry was so precious that further rationalization of the NHS drug supply should be avoided (PSGB 1954, 1956a).

From the Unregulated Market to "Light-Touch" Regulation for the Safety and Efficacy of NHS Drugs

For the first twenty-three years of the NHS, there was no systematic scientific testing and regulatory oversight of new medicines coming into use by the service, even though government expert advisers in 1962 estimated that more than half the new drugs entering the market were not correctly clinically tested by the industry (PSGB 1962a, 1962b). Drug safety and efficacy regulation was not introduced until 1971 when the 1968 Medicines Act came into effect. A national drug regulatory agency, the Medicines Division within the Department of Health (DoH)[2]—the successor of the MoH—was formed with a full-time scientific staff required to review the

2. During the late 1960s, 1970s, and early 1980s, the full name of the DoH was the "Department of Health and Social Services" (DHSS), which subsequently shortened its name to "Department of Health."

data on new drugs compiled by companies. The agency was empowered to permit (or deny) approval of those drugs for the British market according to various techno-scientific criteria of safety and efficacy. Even under the Medicines Act, initially, "old" drugs that had entered the market before 1971 could continue to be used in the NHS without meeting such criteria. There were thirty-six thousand medicinal products in this category, of which four thousand were prescription drugs (Binns 1980). It was not until 1975, in response to a European Economic Community directive requiring all medicines to be reviewed according to modern licensing standards, that the DoH set up a committee to assess the safety and efficacy of these "old" drugs—a task not completed until 1990, nearly thirty years after the discovery of the thalidomide disaster in late 1961, and more than forty years into the life of the NHS (Abraham 1995b).

In 1961, news broke that a tranquilizer known as thalidomide, given to many pregnant women to relax them or help them sleep, had caused many thousands of birth deformities in the United Kingdom and several other European countries. It is often supposed that the thalidomide disaster provoked the U.K. Medicines Act as well as pharmaceutical safety regulation in many other countries, but that assumption is generally overstated. Before thalidomide, in 1959, the Hinchliffe Parliamentary Committee recommended that all new drugs should be subjected to "independent" trials, and that the government should set up a committee to "organize clinical trials of new drugs and interpret their results" (PSGB 1959). In February 1960, the minister of health set up the interdepartmental government review of drug legislation in which the Pharmaceutical Society of Great Britain urged that control of medicine safety and efficacy should be vested with the appropriate ministers (PSGB 1961, 1962c) Indeed, the pharmaceutical industry itself began to see some advantages in rationalizing the legislative patchwork over therapeutic classes that had emerged since the Second World War. In 1959, the ABPI advocated the creation of an "independent" voluntary trust to vet new drugs (Abraham 1995b). The 1961 thalidomide disaster certainly confirmed the need for a formalized system of drug safety regulation; it added to the determination of those already pressing for such reforms; and it extended support for government regulation to wider constituencies, such as the media and the general public. However, the slowness in the introduction of the Medicines Act—ten years after thalidomide—indicates many factors other than thalidomide at work in the evolution of modern drug regulation for the NHS.

To understand the nature of regulation of drug safety and efficacy, it is important to examine those factors. Focus on the thalidomide disaster has

created the popular narrative that the Medicines Act should be understood as the government stepping in to protect public safety. I suggest, however, that it is better to see it as the culmination of a long negotiating process between the industry and the state (including senior members of the medical profession advising the government) about how best to restore public confidence in drugs and the pharmaceutical industry. Those negotiations reveal that protection of industry interests was paramount in formulating safety and efficacy regulation. The government treaded carefully and consulted closely with the pharmaceutical industry about such regulatory developments. As the president of the ABPI pointed out, the DoH was the industry's sponsoring department and had responsibility for the industry's scientific and commercial progress (PSGB 1962d). The industry wanted some regulation both to help rationalize its operations and to raise the standing of its products abroad but not a regulatory system too critical of its brand name products, which were already established in the United Kingdom and export markets (Wheeler 1964).

In 1964, the government established the Committee on Safety of Drugs (CSD), also known as the "Dunlop Committee," after its chair. The CSD reviewed toxicological and clinical safety data submitted by pharmaceutical firms and advised the manufacturers and the government on whether the new drugs in question had been shown to be safe enough to go on the market. With no legal powers, the committee depended on voluntary cooperation from the industry. While its members were not employed by the industry, they were permitted to have direct and/or indirect financial interests in pharmaceutical companies, such as shareholdings and/or research grants, respectively (PSGB 1963a). From the outset, the CSD declared that industry data submitted to it as well as the committee's deliberations about the safety of drugs were to be treated as confidential. Thus, the CSD was sealed off from public scrutiny and accountability (PSGB 1963b). Simultaneously, the committee's regulatory review was deliberately rapid (averaging less than three months) so as not to "exercise a detrimental effect on pharmaceutical research progress by unduly delaying the introduction of a possibly valuable drug or even by preventing its use altogether" (PSGB 1967). Such extensive concern for industry interests reflected a deep-rooted corporate bias, unchecked by the absence of countervailing powers, with real impact on the protection of patients. As a former member of the CSD explained, "Looking back I see only one major error in our performance. We were so aware of the enormous cooperation that we received from the drug industry that the main Committee made every effort it could to see that submissions from firms were handled

as rapidly as possible—as a result . . . . the Adverse Reactions subcommittee and . . . . the work of that subcommittee suffered" (Wade 1983).

The CSD served as a prototype for the formalized safety regulation of the Medicines Act. While the act went beyond arrangements associated with the CSD, three crucial regulatory principles associated with the CSD continued beyond its demise: close involvement of *industry interests*; "light-touch" (and speedy) *regulatory review*; and *secrecy* of decision making. All of these defined the corporate bias endemic to safety and efficacy regulation of NHS drugs.

The close involvement of industry interests may be illustrated as follows. The Medicines Act replaced the CSD with the Committee on Safety of Medicines (CSM), which advised the DoH on the safety and efficacy of all new drugs. The act established a new regulatory body, known as the Medicines Commission, whose role included advising the government on the membership of the CSM. As with the CSD, members of the CSM and the Medicines Commission were permitted to have direct and indirect financial interests in pharmaceutical firms—and many exercised this privilege until 2006 when it was prohibited (Collier 1985; Delamothe 1989). In May 1969, a few weeks after Dunlop was appointed chair of the new Medicines Commission, the pharmaceutical industry was invited to have discussions with the DoH about the commission's functions, structure, and membership (ABPI 1970).

Regarding the "light touch" of regulatory review, the government assured industry that the new regulatory regime under the Medicines Act was to aim for a "Dunlop type" speed of administration, and that, with some of its members drawn from industry, it was unlikely that the Medicines Commission would use its influence to limit the introduction of new products by being unduly exacting in its requirements (PSGB 1968b, 1968a). Indeed, a former chief pharmacist at the DoH who had been closely concerned with the new medicines legislation from 1962–1967, predicted that manufacturers would hardly notice the difference when the CSM took over from the CSD (PSGB 1970). Dunlop echoed this view. Noting that the medical profession depended on the industry's well-being, he warned that laws enacted to assure drug safety and efficacy should not impose unnecessary restraints on the prosperity of the pharmaceutical industry (PSGB 1968a).

Secrecy increased. As civil servants, the full-time regulators at the new Medicines Division became subject to the 1911 Official Secrets Act from the moment of the division's inception. Such official secrecy was designed to control civil servants' unauthorized release of information to the public.

Breaches of the act were punishable by fines and imprisonment (Robertson 1982: 1–91). Moreover, section 118 of the 1968 Medicines Act made it a criminal offense for the Medicines Division and all expert advisers involved in U.K. drug regulation (including the CSM and Medicines Commission) to divulge any information about the medicine licensing process to the public without government authorization. Such intense secrecy legislation was repealed in 2005 under the U.K. Freedom of Information Act, but in practical policy terms, the vast majority of British regulatory review has sought exemption from "freedom of information," remaining largely opaque to public scrutiny.

After the Medicines Act, doctors and patients in the NHS could be confident that new drugs were tested for safety and efficacy in controlled clinical trials and animal studies, though the interpretation and enforcement of scientific standards by industry and U.K. regulators for such testing were not as rigorous as they could have been—permitting some patients to be exposed to unnecessarily toxic drugs (Abraham and Davis 2007). In addition, doctors were brought into the drug regulatory system via the "yellow card" scheme, which asked prescribing doctors to voluntarily report to the regulatory authorities all suspected adverse drug reactions (ADRs) they observed in clinical practice. The scheme was supposed to enable the CSM to track ADRs associated with each new drug on the market. It was intended to provide an early warning system about dangerous drugs that had slipped through the battery of premarket safety testing and regulatory review. However, doctors reported, and continue to report, only between 1 and 10 percent of ADRs (Lumley et al. 1986; Medawar and Hardon 2004: 154; Millar 2001; Pirmohamed et al. 1998; Walker and Lumley 1987). Corporate bias ensured that much stronger regulatory interventions that would have been more effective in protecting public safety (but contrary to industry interests), such as more rigorous premarket regulatory review and restricted release of new drugs to the market, were dismissed.

For example, in 1976 the CSM established a working party to consider ways of supplementing the yellow card system to improve safety regulation (Commentary from Westminster 1976). Dollery and Rawlins proposed a scheme of "registered release" to the working party that would require pharmaceutical companies to complete a quota of (five to ten thousand) patient registrations for a new drug *before* it went on widespread sale (Dollery and Rawlins 1977). Registered patients' results would then be followed in detail. This countervailing intervention by some expert scientists would, therefore, have formally slowed the market release of new drugs but would have provided more time and evidence for assessment

of ADRs before marketing to a potentially huge patient population. The ABPI made it publicly known that it was opposed to a scheme of restricted release for new drugs because it would "unnecessarily inhibit the freedom of doctors to prescribe a new medicine" (Wilson 1977). However, an article in the industry journal *Scrip* suggested that an important reason for industry opposition was that such a scheme would have inevitably reduced sales in the initial period of new drug marketing (CSM Interested in Computerised Monitoring 1976). Significantly, the National Economic Development Council's "sector working party" on the pharmaceutical industry concluded in 1976 that, in order for the pharmaceutical sector to maximize its contribution to a positive balance of payments through expansion of direct export and import substitution, the Department of Health should seek to minimize its interference with the industry's economic performance (News and Notes 1976). In this context, the industry resisted curtailment of its sales by measures such as restricted release, and the CSM was asked by the government to look at ways of helping the industry (PSGB 1976). By the end of 1978, the CSM had abandoned its plans for restricted release of new medicines as being "not practicable" (Range of Post-Marketing Surveillance Schemes 1978). Several members of the CSM and senior regulators at the time have confirmed that the CSM abandoned retricted release largely because of industry opposition (Abraham and Davis 2006: 141–142).

Neither the yellow card system nor the premarket safety testing introduced under the Medicines Act prevented thousands of NHS patients from being severely injured or killed by the beta-blocker Practolol and the antiarthritis drug Opren—the two largest drug disasters in the United Kingdom in the 1970s and 1980s, respectively. In 1972, 501,700 prescriptions were written for Practolol, increasing to nearly 900,000 in 1974 when it became the U.K. market leader among antiangina drugs. The next year it was withdrawn from the market on safety grounds. By 1981, the CSM had received 2,450 reports from doctors describing adverse reactions to the drug, including forty deaths, two hundred cases of life-threatening conditions, 1,130 cases of eye damage, three hundred cases of deafness, and 1,250 serious skin reactions (Abraham and Davis 2006). More than a million NHS patients took Opren by prescription in the early 1980s. It was withdrawn on safety grounds in 1982 but only after an accumulation of reports from doctors that it was suspected of having caused several thousand severe (and often irreversible) skin reactions (photosensitivity and onycholysis) as well as at least ninety-six deaths (Abraham 1994a).

Both these drugs were heavily promoted by their manufacturers to NHS

doctors as therapeutic breakthroughs. In fact, scientific studies showed that the drugs possessed modest efficacy at best and that neither offered significant advance in their respective therapeutic fields. Furthermore, subsequent analysis has demonstrated that more rigorous premarket testing, data collection, safety analysis, and regulatory review could have given much more weight to their toxicity and adverse reactions at that stage, thereby denying them approval for the U.K. market. For example, the U.S. Food and Drug Administration (FDA) refused to approve Practolol for their market and the Swedish authorities withheld marketing approval for Opren in their country (Abraham 1994a; Abraham and Davis 2006). Indeed, the U.K. regulatory authorities had to withdraw from the market twice as many new prescription drugs as the FDA from 1971 to 1992, largely because they had approved more unsafe drugs than their American counterparts (Abraham and Davis 2005).

Despite these human disasters, weak regulation persisted, and the pharmaceutical industry continued to press for more rapid (and arguably even weaker) regulatory review throughout the 1980s. This was often accompanied by the threat that ostensibly onerous regulation would cause "early developmental work on new drugs to go abroad to the detriment of British industry and U.K. departments of pharmacology"—a perspective eventually adopted by the U.K. regulators themselves (Griffin and Long 1981). In response, the government conducted a review of medicines regulation and decided to take up the pharmaceutical industry's suggestion that manufacturers would be willing to pay the cost of regulatory review if that were to result in a more "efficient service," by which was meant more rapid approval (Evans and Cunliffe 1987; *Scrip* 1988a). Previously, the Medicines Division had been funded 65 percent by licensing application fees from the pharmaceutical industry and 35 percent by the government via taxes (*Scrip* 1988b). Following this review, in 1989, the Medicines Division was abolished and reconstituted as the Medicines Control Agency (MCA), which was to be entirely funded by industry fees—further consolidating corporate bias. In effect, the MCA came to be run as a business, selling its regulatory services to the industry and promoting itself as the fastest licensing authority in the world for new drugs (*Scrip* 1991).

Supporters of this new arrangement argued that it saved taxpayers' money, which could be diverted into the NHS. It was also suggested by government and industry that important new drugs would reach NHS patients faster. On the other hand, the drug regulatory agency's complete reliance on pharmaceutical industry fees for its income might compromise its independence, making it vulnerable to industry demands for rapid

regulatory review that would then minimize checks on the safety and efficacy of NHS drugs. The optimistic proposition that comprehensive industry funding would lead to increased access to new drugs needed by NHS patients has proven to be unfounded. The number of new drug innovations and the number of new drugs offering significant therapeutic advance have both fallen in the decade from the early 1990s (Centre for Medicines Research 2005; Charles River Associates 2004). Regarding regulatory rigor, it is interesting to note that until mid-1988, drug product licenses were suspended or revoked by the Medicines Division at an average rate of about ten per year. Yet, over the next three years no drug lost its license until Upjohn refused to withdraw Halcion (Abraham and Sheppard 1999).

Moreover, major drug safety problems affecting many thousands of NHS patients continued under the funding regime of the MCA and its successor (since 2003), the Medicines and Healthcare Products Regulatory Agency (MHRA). Pirmohamed and colleagues (1998) estimated that ADRs accounted for 5 percent of all hospital admissions in the United Kingdom and occurred in 10 to 20 percent of hospital patients. Some of these drug safety problems were investigated in an eight-month inquiry by the U.K. Parliament's House of Commons Health Committee into "the influence of the pharmaceutical industry" (and presented in a report by that name) in 2005. The HCHC heard that severe withdrawal reactions and suicidality had occurred since the early 1990s among many patients taking Prozac-like antidepressants, known as selective serotonin reuptake inhibitors (SSRIs). The introduction of SSRIs led to a threefold increase in NHS prescriptions of antidepressants between 1990 and 2000. By 2005, NHS prescriptions for antidepressants matched those of tranquilizers (such as Valium) at their peak in the late 1970s (HCHC 2005: 85–88).

For ten years, the manufacturers of these drugs asserted that it was "rare" for patients taking them to experience withdrawal reactions. That view was echoed by the MCA, which conducted three reviews of SSRIs based on yellow card data that produced misleadingly low estimates of the risk. In 2003, after an expert working group of the MHRA went public with its more thorough review of the evidence, the manufacturers and the regulators revised their risk estimate upward from "rare" to "25 to 30 percent" (ibid.: 81–88). The MHRA's expert working group also published warnings about use of SSRIs by children, but only some years after concerns about the association of suicidality with these drugs was first raised. The HCHC report also revealed that the MCA/MHRA "failed to warn of the lack of evidence (since the early 1990s) of SSRI effectiveness in mild

depression, suggesting that most users might expect minimal benefit when exposed to significant risks" (ibid.: 86).

Just as the yellow card postmarketing surveillance system failed to warn of safety problems with Practolol in the 1970s, the HCHC discovered how it had failed to detect the dangers of the antiarthritis drug, Vioxx, which was introduced into the NHS in 1999. It is estimated that Vioxx may be associated with tens of thousands of avoidable heart attacks and strokes in the United States (and hence, by extrapolation, several thousand in the NHS), probably making it the worst drug disaster in the history of the modern pharmaceutical industry (Topol 2004). However, the yellow card scheme recorded a steady (and *small*) number of heart attacks associated with Vioxx in the United Kingdom from 1999 to 2004, when the drug was withdrawn worldwide on safety grounds. The yellow card scheme recorded just six heart attacks in 1999, nine in 2000, seven in 2001, five in 2002, seven in 2003, and four in 2004, even though the number of U.K. prescriptions rose from 162,600 in 1999 to 2,128,600 in 2003, and the actual number of heart attacks must have been very much greater (HCHC 2005: 31).

Pharmaceutical Profits and the NHS: The Price of the State's Conflicting Objectives

The NHS's expenditure on pharmaceuticals has continued to rise — 80 percent of which may be attributed to general practitioners (GPs), also known as family physicians. It rose by 70 percent between 1980 and 1993, when it reached £3.3 billion, and the growth in expenditure has accelerated. In 2007, the NHS spent £8 billion on brand-name drugs, and the overall annual bill for pharmaceuticals stood at £11 billion (Office of Fair Trading [OFT] 2007: 2–9). Apart from increases in the number of prescriptions, partly due to an aging population structure, the main reason for the rising NHS drug bill is the high price of pharmaceuticals. The average price of drugs purchased by the NHS has risen annually in real terms by between 7 and 13 percent since 1980. Overall, pharmaceutical prices in the United Kingdom have historically been higher than in the rest of Europe (ibid.: 4–5). While the price of existing medicines has risen by only about 2 percent per year, newly introduced pharmaceuticals are very highly priced. The latter are particularly costly to the NHS because they are heavily promoted to the medical profession by pharmaceutical companies and are most prescribed. Indeed, the OFT (ibid.: 4) found that one drug alone was overpriced to the tune of £350 million in costs to the NHS in 2005.

Neither prescribers nor patients in the NHS are sensitive or even aware of the prices of the drugs they use. This is particularly true in primary care. According to the OFT (ibid.: 2), surveys suggest that GPs have a poor knowledge of the prices of some of the most widely prescribed drugs in the United Kingdom. As for NHS patients, they contribute, via prescription charges, to less than five percent of expenditure on prescription pharmaceuticals. These elementary features of the relationship between "consumer demand" and the setting of prices for NHS drugs, together with the consequential need for a system of pharmaceutical price regulation has been recognized by government as early as the 1950s.

The pharmaceutical industry's influence over NHS drug prices has been very significant. No other interest group has rivaled the industry's access to government on the question of pharmaceutical pricing. In the United Kingdom, the prices of branded medicines are regulated by a *voluntary* arrangement between the government's DoH and the pharmaceutical industry, known as the Pharmaceutical Price Regulation Scheme (PPRS). It controls prices indirectly by controlling companies' profits. As it is primarily a profit-control scheme, the price of a new drug at launch is entirely a matter for the company concerned (ABPI 1993). The PPRS was first introduced in 1957 and is renegotiated periodically by the government and the ABPI, usually every five years. The overall official objectives of the PPRS were, and remain, to secure the provision of safe and effective medicines for the NHS at reasonable prices and to promote a strong and profitable pharmaceutical industry capable of sustained research and development (R&D) expenditure. As such, the regulation of NHS drug prices contained conflicting objectives from the outset. One set of objectives was in the interest of the NHS and arguably the wider public, while another set was designed to protect the industry's interests in extracting high prices from the NHS. The British government's approach to this policy challenge has been to strike a "balance" between these conflicting objectives and interests. However, it has turned overwhelmingly to the pharmaceutical industry in order to formulate the details of where that balance should be struck with few, if any, countervailing powers in evidence. As such, I suggest that regulation of NHS drug prices has also been characterized by a form of corporate bias.

The PPRS applies to all companies with sales of branded, prescription medicines to the NHS of over £1 million per year, though only companies whose annual sales exceed £25 million are required to supply detailed financial information to the government. In 2005, the forty-four companies whose sales exceeded £25 million accounted for 94 percent of the

total amount the NHS spent on purchasing brand-name pharmaceuticals. The scheme is based on profit targets negotiated between the DoH and individual companies. The latitude within which companies have been permitted to miss those targets has widened over the years (OFT 2007: 3). Under the scheme, it is currently acceptable for companies to be within 40 percent above or below their annual targets, but profits more than 40 percent above the agreed target are deemed excessive and supposed to be corrected either by requiring the company to reduce its prices or make a repayment of the excess to the government (HCHC 2005: 34–35).

The PPRS, together with its conflicting objectives, has been maintained for over fifty years. Its maintenance is testimony to the reluctance of the state to develop a price-control system that better protects the interests of the NHS over and above the trade interests of the pharmaceutical industry. Arguably, such corporate bias reflects a deeper political philosophy of the British state that has persisted for decades at the heart of government—a philosophy well illustrated in a November 1976 speech by James Callaghan, the British prime minister, who stated that, when the chips are down,[3] "we must give absolute priority to industrial needs ahead of even our social objectives," as well as by the declaration of then Secretary of State for Industry Eric Varley "that a profitable manufacturing industry provides the basis for all the social improvements we want to see" (ABPI 1977).

For as early as 1967, a government-commissioned committee, chaired by Lord Sainsbury, concluded that "an examination of the reasonableness of overall profits without a detailed examination of the prices of individual medicines is inadequate" (Sainsbury Committee 1967: 51). In the negotiation of profits, each company is allowed to include expenditure on promotion and research in the assessment of its costs, as well as on manufacturing and distribution. Such costs are then set against sales to estimate profits. By claiming large costs, companies can provide estimates of relatively small profits, enabling them to charge high prices to the NHS (HCHC 1994: xvi). Hence, the PPRS encourages, or at least does not discourage, companies' drug promotion of new branded drugs, even though it is widely agreed that such promotion is one of the drivers of the growing NHS drug bill. While the PPRS has apparently sought to reduce the cost of pharmaceuticals to the NHS by curbing prices, it has simultaneously created favorable conditions for the growth of one of the other major causes of the NHS drug bill.

3. At this time, the British chancellor of the exchequer felt it necessary to go to the International Monetary Fund for a loan of £3.9 billion (Thompson 1984: 286).

If a company's profits are more than 40 percent below the agreed target, it may apply to the government to increase its drug prices within the PPRS. Yet, as the HCHC (1994) concluded, a major drawback of this practice is that, if the NHS is successful in persuading GPs and hospitals to prescribe more generics instead of the more expensive, but no more effective, brand-name drugs in order to release scarce resources to other types of health care, then the manufacturers of the brand-name products are entitled to increase the price of their products to the NHS. Pharmaceutical companies do not set the price of individual products in isolation. Rather, they adopt a pricing strategy for their entire range of products, designed to produce a given return on capital. If sales of a particular brand-name product decline due to generic substitution, then a company may seek to compensate for this under the PPRS by increasing the prices of their other branded products for which there is no generic equivalent. The consequence of the latter scenario is that it frustrates efforts by NHS professionals and managers, as well as other parts of the government, to reduce the amount the state spends on pharmaceuticals in the health service.

Furthermore, the operation of the PPRS relies on companies' estimates of their expenditure on R&D. The difficulty faced by the DoH in checking the accuracy of these estimates about every new brand-name drug is indicated by the fact that claims about the average cost of R&D for such drugs vary at least fivefold (McIntyre 1999). As early as 1983, the government's comptroller and auditor general found that the DoH did not have the resources to check on individual companies and that it had inadequate evidence to establish objectively the efficiency of the industry (Public Accounts Committee 1983). This problem has persisted for decades and was once again reiterated by the OFT (2007: 3) when it observed that there were "a number of major practical difficulties [in] making meaningful profitability assessments in the pharmaceutical sector—not least the fact that companies have an increasingly global cost base and a high level of intangible capital, which is only indirectly recognised through the scheme." To add to these difficulties, critics have long argued that transnational pharmaceutical companies artificially inflate their manufacturing costs by pretending to charge themselves steeply for cheap chemicals imported from foreign subsidiaries—a practice known as "transfer pricing" (Collier 1989: 118–120).

Even if one accepts both the allowances for and the estimates of promotion, R&D, and profits negotiated by the pharmaceutical companies and the government, problems of enforcement have been extensive. In 1994, the HCHC reported that during the four-year period 1988–1991, of the

sixty companies participating in the PPRS, an average of thirty-eight each year were assessed by the DoH as having made profits above the upper limits of their target. Thus, about two-thirds of the major pharmaceutical suppliers to the NHS made excessive profits; of these, an average of only one company each year was required to make price reductions (HCHC 1994: xviii). The OFT (2007) reported that the profit repayments in the 1999–2004 period of the PPRS were also negligible—representing just 0.01 percent of company PPRS revenues over the period.

In 2004, the PPRS was again renegotiated. After nine months of talks, the ABPI and DoH agreed to the equivalent of a 7 percent price reduction for branded prescription medicines purchased by the NHS in exchange for favorable incentives for the industry's R&D, such as an increased allowance for R&D costs and financial rewards for the development of innovative medicines, especially for children. The government claimed that the new agreement would save the NHS £1.8 billion over five years. John Reid, then the secretary of state for health, hailed the new deal as a win-win situation that was good value for money for the NHS and the taxpayer and good for the industry because it provided incentives for research and innovation (Billion-Pound Price Cut Won for NHS Medicines Bill 2004). Yet, the NHS drug bill remained enormous. In 2007, the government's Office of Fair Trading concluded that even the prices negotiated by Reid's department were not at all a good deal for the NHS (OFT 2007).

According to the OFT (ibid.: 4), under Reid's deal the NHS was paying at least £500 million per year too much for brand-name prescription drugs, and some NHS drugs were priced at ten times the cost of equally beneficial alternatives. In short, under the PPRS, drugs with very similar clinical effects could have widely divergent prices. Consequently, the scheme has not ensured that the NHS can make the best use of its resources to improve patient health. Moreover, the inadequacies of the PPRS have other unintended effects for both the NHS and health care in other countries. Since 1999, the National Institute for Health and Clinical Excellence (NICE) has conducted cost-effectiveness assessments of some new drugs to establish whether they should be recommended for use in the NHS. Such assessments, which take into account the price and clinical benefit of drugs, are undermined if the drug prices used are inappropriate. Outside the United Kingdom, many other countries, making up about 25 percent of global pharmaceutical demand, set their prices with reference to those in the United Kingdom (OFT 2007: 4). Thus, the flaws of the PPRS may be passed on to the national health care systems of other countries.

The OFT (2007) recommended a complete overhaul of the PPRS so

that the price of a drug was directly linked to its therapeutic value to NHS patients rather than to the financial cost of industry research and promotion. The ABPI responded by saying it was important that the transnational pharmaceutical industry felt valued by the NHS in order to keep research and innovation in the United Kingdom (NHS Drug Costs to be Renegotiated 2007). It remains to be seen whether the government will decouple itself from the corporate bias that has ruled pharmaceutical price regulation for the last fifty years and take up instead the recommendations of the OFT in full, including the abolition of the PPRS in favor of a pricing policy linked to patient benefit. Reid's renegotiation was supposed to run until 2010, but in early 2008 the government entered into dialogue with the ABPI with the intention of cutting the NHS drugs bill by a further 10 percent annually—about £1 billion per year (Ministers Seek to Cut NHS Drugs Budget 2008).

Clinical Autonomy, Industry Influence, and the Interests of the State: From "Rational" Prescribing to Cost-Effectiveness and NICE

Until the mid-1980s, NHS GPs could prescribe virtually whatever medicines they pleased, confident that the health service would foot the bill. They enjoyed extensive clinical autonomy. The JCP had sought to rationalize NHS drug use, but was essentially advisory and lacked sustained determination. The Medicines Act legislated that all new NHS drugs should be more efficacious than placebo, and between 1975 and 1990 the DoH's Committee on Review of Medicines gradually removed from the market nearly all the "old" drugs lacking evidence of such efficacy. However, these measures did little or nothing to rationalize the costs of prescribing with respect to choices between drugs possessing therapeutic efficacy.

This began to change in 1984 when Kenneth Clarke, the minister of health, introduced a limited list of medicines, which implied that approximately eighteen hundred preparations would no longer be paid for by the NHS. The list encouraged rational prescribing, since nearly all the medicines excluded were therapeutically unimportant. Nevertheless, the pharmaceutical industry, some of whose products would lose a major market, led a fierce campaign against the limited list, gaining the support of the British Medical Association (BMA) and the Labour Party (Medawar, Rassaby, and Guthrie 1992: 176–180). Consequently, the government gave ground to the industry and its assimilated allies. By the end of 1985, the government's limited list was not so limiting on doctors' prescribing.

In 1986, the DoH established the selected list scheme — a "watered-down" limited list. To decide which products to add to the selected list of drugs that could not be prescribed on the NHS, the secretary of state for health established an advisory committee to advise "in order that drugs to meet all real clinical needs can be provided as economically as possible under the NHS" (HCHC 1994: xxv). The 1986 selected list scheme pertained to just seven therapeutic categories, namely mild to moderate painkillers, indigestion remedies, laxatives, cough and cold remedies, vitamins, tonics, and benzodiazepine sedatives and tranquilizers. At a national level, GPs had been advised in the British National Formulary (British Medical Association and Pharmaceutical Society of Great Britain 1981) that the drugs selected in these categories were of marginal therapeutic importance. However, the 1986 selected list was of policy significance because it established the principle that the central state, advised by expert medical scientists, could dictate to doctors which drugs of proven efficacy were prescribable on the NHS.

In 1992, this principle was pushed further when the government extended the selected list to other therapeutic categories, such as antidiarrheal drugs, drugs for allergic disorders, appetite suppressants, drugs for vaginal and vulval conditions, contraceptives, drugs used in anemia, topical antirheumatics, drugs acting on the ear and nose, and drugs acting on the skin. Unlike the 1986 list, these ten new categories contained many drugs central to patients' treatment. Thus, the 1992 list raised the prospect for the first time that therapeutically effective drugs could be ineligible for prescription on the NHS because there existed other drugs with evidence of greater effectiveness or cheaper ones of equivalent effectiveness (HCHC 1994: xxiv–xxv).

For many GPs, this list represented an unacceptable curtailment of their right to exercise unfettered clinical judgment in the best interests of their patients and might even prevent patients from receiving the most appropriate treatment. As for the industry, it claimed that the list acted as a disincentive to pharmaceutical firms to undertake research within the therapeutic categories covered by the list, thereby undermining the prospect of new treatments for patients with those conditions (ibid.: xxv–xxvi). However, as the government pointed out, there was no evidence that long-established local hospital lists had had any negative effect on pharmaceutical innovation, while there was evidence that industry innovation in these therapeutic areas was declining *before* the introduction of the 1992 list. The government also took the view that doctors' clinical "freedom" should not extend to prescribing drugs on the NHS for which there existed

more cost-effective alternatives (DoH 1994a). Furthermore, in 1994 the U.K. government's Audit Commission reported that more rational prescribing by doctors could save the NHS over £400 million per year (Audit Commission 1994).

The government's attempts to control NHS prescribing centrally began to unravel when Secretary of State for Health Frank Dobson tried to limit doctors' prescriptions of Viagra—the first successful oral treatment for erectile dysfunction. When it was approved for the U.S. market in March 1998, it was prescribed at a rate of twenty thousand per day (Viagra Breaks All Records in the U.S. 1998). Between April and June 1998, 2.9 million Viagra prescriptions were written (U.S. Insurers Turn Down Viagra 1998). Two months later, the supranational EU drug regulatory authorities approved it for marketing across the European Union, including the United Kingdom (Viagra Recommended for EC Approval 1998). This presented the immediate problem of the implications for public health provision if the NHS had to pay for millions of Viagra prescriptions. To offset this difficulty, Dobson sought to manage demand for Viagra by restricting its prescription and declaring that doctors' prescriptions would only be reimbursed by the NHS for patients who "clinically needed" the drug (No Viagra Reimbursement in EU? 1998).

Given that Viagra was a new innovative drug with clear evidence of therapeutic advance, it could not reasonably be placed on the selected list because, though expensive, there was no other drug in its therapeutic category that could match its effectiveness. Hence, in September 1998, the DoH sent a circular to NHS doctors advising them not to prescribe Viagra "save in exceptional circumstances" (U.K. Rules DoH Viagra Circular Unlawful 1999). However, Pfizer, the manufacturer of Viagra, challenged the legality of the circular in the court in May 1999. The judge found in the company's favor, concluding that the health secretary could not lawfully deter doctors from complying with their statutory obligation to prescribe a drug for which there was a clinical need when the drug was not placed on the selected list.

The Viagra case demonstrated to the government that the selected list alone was an insufficient mechanism for achieving the complex goal of cost-effective drug prescribing in the NHS because it failed to take account of the possibility that a new therapy could be uniquely clinically effective but very poor value for money when cost-effectiveness was forced to be considered in the context of overall affordability in the health service. Moreover, such cost-effectiveness analysis was something that local formulary committees in NHS hospitals and GP clinics had strug-

gled to achieve and apply, due to lack of expertise and resources (Sloan, Whetten-Goldstein, and Wilson 1997). Even in 2007, only in exceptional cases was decision making about local formulary lists informed by cost-effectiveness analysis (Williams and Bryan 2007). Consequently, in April 1999, the government established the new expert Special Health Authority, NICE, which was to review evidence and make scientifically robust recommendations to doctors and the NHS about therapeutically efficient and cost-effective prescribing on a national level that would minimize interregional variation. The DoH let it be known that it expected NICE recommendations to be followed "to the letter" (No Flexibility in U.K. NICE Advice 1999).

Evidently, the controversies over the eligibility of drug prescribing on the NHS were part of a battleground over clinical autonomy versus managerialism between NHS doctors and the state (Britten 2008). However, there are clearly other relevant issues worthy of note, such as the extent to which countervailing powers within the state asserted their own interests in conflict with industry, thereby disowning corporate bias on this particular issue, and the fact that it was the power of industry opposition in campaigns and courts to deconstruct policies more than any other factor that drove the state to develop such strong convictions for robust decision making and the establishment of NICE. Seen in this light, the fate of clinical autonomy depends not merely on the managerial tendencies of the state. It also depends on a balance and interaction of interests, especially the extent to which the pharmaceutical industry is either allied with the state or is involved in assimilating the medical profession into an alliance against the countervailing powers of the state. This is key to understanding how pharmaceutical cost-effectiveness policies in the NHS have fared since the inception of NICE.

Annually, NICE receives about £15–£20 million from the government and is accountable to the secretary of state for health, who appoints the institute's chair and board of nonexecutive directors. Its formal aims are "to promote clinical excellence and the effective use of available resources in the NHS, ... to promote the appropriate use of those interventions which offer good value to patients and to discourage the use of those which do not, ... [and] to ensure that . . . it is sympathetic to the longer term interest of the NHS in encouraging innovation of good value to patients" (NICE 1999). NICE appraises particular technologies relevant to the NHS and provides evidence-based recommendations about their cost-effectiveness for the health service (Williams and Bryan 2007). Such appraisals have covered surgical procedures; medical devices; screening

technologies; and, since 2005, public health interventions, but the majority have focused on pharmaceuticals (DoH 2002a).

It is vitally important to pharmaceutical companies that when NICE reviews their products, it recommends them for use in the NHS, because the health service comprises the lion's share of the prescription drug market in the United Kingdom. In October 1999, NICE published its appraisal of Relenza, a drug marketed for the treatment of influenza by Glaxo Wellcome (now GlaxoSmithKline). NICE recommended that Relenza should not be used in the NHS because, even when used early in patients with confirmed influenza, it was likely to reduce the duration of symptoms by only one day, and there was insufficient evidence about the drug's effects in at-risk groups (Why Not Zanamivir? 2001). Thus, NICE asserted its regulatory function to prevent pharmaceutical use that was not good value for patients or the NHS, irrespective of the manufacturer.

Glaxo Wellcome, however, responded by leading protests in the media and beyond, which, joined by other pharmaceutical companies, included threats to move pharmaceutical laboratories out of the United Kingdom (Drug Companies Join Flu Protest 1999). In November 2000, NICE issued new guidance on Relenza, recommending the drug for use in at-risk individuals based on new evidence prepared by the manufacturer. However, three months later, the *Drugs and Therapeutics Bulletin* (*DT&B*), a popular and highly respected publication among NHS doctors, which was subsidized by the DoH, offered advice contrary to NICE's November 2000 recommendation and questioned whether there had been any change in the scientific evidence base to support NICE's altered guidance (Guidance over Anti-Flu Drug "Wrong" 2001). A year later, the HCHC (2002: 11) heard from several prominent members of the medical profession that the public controversy over Relenza had left many doctors and NHS managers with the impression that "maybe NICE had been got at, that it had made a change in response to major political pressure from the media and the drug industry."

Indeed, such concerns reflected the shift in professional norms that had taken place regarding rational prescribing in the NHS since the limited and selected lists of the mid-1980s. Particularly in many NHS hospitals, doctors' prescribing had become subject to drug and therapeutic committees, which demanded high standards of benefit-risk ratio (sometimes higher than NICE) before allowing drugs on the hospital formulary. The NHS also established area prescribing committees supported by multidisciplinary teams of professionals to improve guidance for GPs in primary care (HCHC 2005: 39–40). Neither these developments nor the introduc-

tion of NICE during the 1990s and 2000s received as much opposition from the medical profession as the lists of the 1980s.

As the pharmaceutical industry found it more difficult to assimilate allies from the NHS and the medical profession in general, it extended its coalition building with specific patient groups and concomitant medical specializations, as illustrated by the governance of beta interferon. The government's handling of whether beta interferon should be prescribed on the NHS for the treatment of multiple sclerosis (MS) raised issues similar to those surfaced by Relenza. MS is a disabling degenerative neurological disease affecting over eighty-five thousand people in the United Kingdom. The beta interferons and glatiramer acetate were the only treatments when the former emerged on the international market (Crinson 2004). In 1995, just before beta interferon was licensed in the United Kingdom, the DoH was extremely concerned about its potential costs to the NHS—£10,000 per year per patient. Treatment of all MS patients with beta interferon would have cost 10 percent of the entire NHS drug budget (New 1996). For this reason, beta interferon was one of the first drugs to be assessed by NICE, whose preliminary appraisal in July 2000 was that the drug should not be funded by the NHS (Sculpher, Drummond, and O'Brien 2001).

The preliminary appraisal was confidential in order to protect the share price of the drug. However, it was leaked to the media (Crinson 2004). Consequently, the pharmaceutical manufacturers, MS patient groups, consultant neurologists, and the Royal College of Nursing campaigned and appealed against NICE's preliminary assessment, including challenges to the institute's scientific methodology of calculating treatment cost per quality-adjusted life year (QALY). Nevertheless, having considered these appeals, NICE decided by November 2001 that beta interferon was still not cost-effective enough for use in the NHS, though the institute's final appraisal guidance report was not published until February 4, 2002 (NICE 2002).

Meanwhile, the DoH negotiated a "risk-sharing scheme" with the pharmaceutical manufacturers (Biogen, Teva-Aventis, and Serono) that would see NHS providing funding for beta interferon prescriptions as if NICE had given a positive recommendation (DoH 2002b). The government presented the risk-sharing scheme as clinical research intended to confirm the cost-effectiveness of the drug via postmarket monitoring, but it lacked many of the scientific standards of a clinical trial (Sudlow and Counsell 2003). From late 2002, the government's scheme imposed a statutory obligation upon the NHS to fund the prescribing of beta interferon. In return, the manufacturers agreed to reduce slightly the cost of the drug

to the NHS to bring it closer to being within (though not actually within) NICE's acceptable limits of treatment cost per QALY (Crinson 2004). In this case, the manufacturer had marshaled a coalition, including elements of the state itself in order to subvert the adverse commercial effects of cost-effectiveness regulation of NHS drugs. By 2002, NICE had recommended the vast majority (twenty-eight out of thirty-one) of the treatments and interventions it had appraised either for routine or selected use with a net financial impact on the NHS of *increased* costs of £135 million to £155 million (Dent and Sadler 2002). This raises the question of whether NICE has been resilient enough to withstand regulatory capture by pharmaceutical industry interests. At the very least, one can conclude that NICE has seemed vulnerable in the face of orchestrated opposition by the industry and its tactically opportune allies within government, the medical profession, and patient groups.

Furthermore, risk-sharing schemes seem set to increase and possibly become a permanent feature of the pharmaceutical industry-NHS-NICE landscape. In 2007 Professor Mike Richards, the National Cancer Director, was asked to consider postlicensing payment mechanisms that could accelerate patients' access to cancer drugs on the NHS. The following year, he recommended that the NHS should negotiate with pharmaceutical companies to obtain lower prices for new drugs via risk-sharing arrangements that would also increase their cost-effectiveness — and hence approval by NICE (British Oncology Pharmacy Association 2008). Several types of risk-sharing schemes are currently under way, including the following: (1) the NHS purchases the drug at full price but may retrospectively claim back expenditure for cases in which patients did not respond; (2) the first cycle of treatment with the drug is free to the NHS, but further cycles must be purchased at nearly full price (i.e., 95 percent of full price); and (3) the NHS receives the drug at a discounted price after specific preagreed levels of expenditure have been reached at full price (HCHC 2008). Such schemes may be regarded as ways for pharmaceutical companies to gain access to NHS markets by bypassing, or at least redefining, the role of NICE, which must recalculate cost-effectiveness in terms more favorable to the industry.

The vulnerability of NICE to such industry manipulation is accentuated by the corporate bias embedded in the limitations of the institute's pharmaceutical appraisals. The institute has neither routine access to relevant unpublished data nor the right to make public all the unpublished data it consults (HCHC 2002, 2005). From the outset, there has been no legal requirement for pharmaceutical manufacturers to supply NICE with all

the relevant information about drugs under assessment (or even to have their products assessed by NICE, though no manufacturers have refused to date). NICE can readily review all the relevant published data/evidence, but its access to unpublished data depends on whether the drug companies and/or the licensing authority, the MHRA, are willing to provide such data. This was revealed most dramatically in 2003 when NICE concluded that SSRI antidepressants were safe for children from a review of the published evidence, but reached the opposite conclusion after also reviewing the unpublished data, eventually released to NICE by the MHRA. Furthermore, even when pharmaceutical firms and/or the MHRA offer unpublished data, they are often supplied in confidence. Consequently, NICE does not necessarily control the selection of unpublished data that it reviews (allowing obvious problems of selection bias by manufacturers) and part of the evidence basis for its decisions may lack transparency and accountability to other interests, including NHS doctors and patients. Under these conditions, the capacity of NICE to act as, or to lead, a countervailing power against corporate bias must be questionable.

NICE was also established to tackle the problem of the "postcode lottery" for treatment. In this situation, some new drugs were available on the NHS to patients whose local health authorities had deemed the drugs cost-effective, but they were unavailable elsewhere (DoH 1998). This issue emerged as a public controversy in the media and the courts in the late 1990s, especially over patients' access to beta interferon for MS and taxanes for ovarian cancer (Women Caught in Cancer Care Lottery 1998). For example, in 1996 the decision by some local health authorities not to fund beta interferon for MS patients in their areas was challenged in the courts by an MS patient who had been denied such treatment by the North Derbyshire health authority. In July 1997, the court ruled in the patient's favor and he subsequently won the right to treatment (Crinson 2004: 35). NICE was to provide definitive nationwide recommendations that would end the "postcode lottery."

Success in so doing has been limited, partly because NICE does not review all new drugs; in addition, sometimes its appraisals are not completed until two years after a drug has been launched to the market. HCHC (2008) recommended that all new drugs should be assessed by NICE between the time of licensing and launch, using a quicker, less thorough process and a lower cost-effectiveness threshold. On this recommendation, the initial appraisal would be followed by a full appraisal using the normal threshold range. The aim would be to ensure that obviously cost-effective treatments would be available to NHS patients earlier, thus

neutralizing some or all of the public controversies over patients' access to new drugs. NICE rejected this twin-track approach because it did not allow for effective scrutiny of the evidence (NICE 2008). However, the DoH (2008) accepted the need for accelerated NICE appraisals, so that the majority of the institute's guidance would be provided "within a few months" of a significant new drug's launch. On the other hand, publication of NICE guidance has sometimes led to pressure from patient groups sponsored by industry to make excessive and inefficient use of the new drugs recommended by NICE (e.g., rosiglitazone for diabetes). Under such circumstances, clinicians can use NICE guidance as justification for heavy prescribing of new drugs — as occurred with the COX-2 inhibitors to treat patients with arthritis (Dent and Sadler 2002).

This relates to wider "rationing" issues about the impact of NICE guidance on the resource priorities of health authorities and about the relationship between those priorities and the selection of technologies for appraisal by NICE (Britten 2008; Light and Hughes 2001). For example, NICE's recommendation of a treatment for reducing the symptoms of influenza by one day may command the same access to resources as recommended cancer treatments. Moreover, resources set aside for those interventions that receive a positive NICE recommendation may have to be withdrawn from some other treatment that is not reviewed by NICE. In this respect, a danger is posed of producing another undesirable form of rationing based on whether a patient has a "politically correct" disease. Health authorities have complained that NICE's focus has placed undue emphasis on expensive drug treatments at the margins of health care rather than treatments of the greatest benefit to the population as a whole. The urgent priority given to an appraisal of beta interferon was driven by the fact that the industry had produced a very expensive innovation demanded by organized patient activism (HCHC 2002: 34–37). There is evidence, therefore, that NICE's objective to be "sympathetic to the longer term interest of the NHS in encouraging innovation" may be in tension with its health policy objective of nurturing cost-effective use of drugs in the NHS overall.

Pharmaceuticalization, Consumerism, and Ideology

In analyzing the response of the state to doctors' apparent irrational prescribing and to the demands of patients to access new drugs on the NHS, one must also scrutinize the wider context that facilitates such prescribing and demands. In particular, the complex structural changes since the

1980s in the ways drug companies have attempted to influence NHS doctors' prescribing need to be unraveled. Pharmaceutical advertising and promotion are huge and growing. Between 1995 and 2005, research staff numbers in the U.K. pharmaceutical industry fell by 2 percent, while marketing staff numbers increased dramatically, perhaps by as much as 59 percent (HCHC 2005: 58). Research shows that promotion and advertising affect prescribing,[4] but they are, in effect, self-regulated by the industry in the United Kingdom—an extreme form of corporate bias in governance (Lexchin 1993). Such regulation is entirely responsive and retrospective, rather than preventive. For example, in April 2002 Schering ran a problematic advertisement about its product Yasmin, which the *DT&B* publicly declared was misleading in August 2002. Initially, Schering threatened to sue *DT&B*, but withdrew this threat after the Advertising Authority, prompted by *DT&B*'s complaint, found the advertisement to have breached advertising regulations on eleven counts in November 2002. It was not until December 2002 and February 2003, respectively, that the company was forced to withdraw the advertisement and then publish a corrective statement—ten months after the product had been launched and prescribed by many NHS doctors (HCHC 2005: 62–63).

Probably more influential on NHS doctors, however, are the more subtle aspects of drug promotion involving the integration of senior members of the medical profession and medical science into pharmaceutical marketing strategies. Both during premarket drug development and after licensing, pharmaceutical companies may hire public relations firms to create an exaggerated favorable media and professional reception as soon as a research article shows their drug in a positive light. Conversely, companies may delay publication of findings that reveal problems with their drug by demanding much higher standards of proof for "negative" results, such as "confirmatory" repeat studies done by "loyal" internal company scientists (Abraham 1994a, 1995b). Frequently, "negative" findings about drugs are not published at all, leading to a systematic bias in medical literature read by NHS doctors. This is mainly due to drug companies' reluctance to submit articles showing their products in an unfavorable light, though it is also partly due to journals' preference to publish positive results (HCHC 2005: 55–56; Lexchin et al. 2003).

Pharmaceutical companies integrate expert members of the medical profession into their promotion strategies by first paying them grants/

4. Typically, doctors claim that their own prescribing is not affected by advertisements but claim that the prescribing of other doctors is so affected.

consultancies to be involved in the development of their products and then funding them to act as "opinion leaders" who speak favorably about a particular drug at various symposia attended by doctors. This assimilation of allies may be combined with publication via special supplements of journals; these supplements receive little independent peer review and their editors are the company-sponsored "opinion leaders," working in collaboration with scientists and "medical writers" employed by the manufacturer (HCHC 2005: 56–57). Before publication, significant editorial changes may be made to scientists' manuscripts, portraying a drug more positively than initially intended by the author (Abraham 1994b). Indeed, many industry-sponsored medical articles might not be written by the medical researchers under whose name they appear in publication, but rather composed by professional medical writers working for the manufacturer — so-called ghostwriting (HCHC 2005; Healy 2006). Ostensibly to save the time of busy medical experts, such ghostwriting may extend market size by promoting the "off-label" use[5] of new drugs, as is believed to have occurred with the prescribing of SSRIs to children on the NHS (HCHC 2005: 54).

Doctors' continued prescribing of pharmaceutical products, and hence pharmaceuticalization, is also facilitated by drug companies' strategies to contain criticism. This may involve withdrawal of funding from institutions that provide platforms for the critics' views, attempts to prevent further publication of critics' data, or using experts supportive of the company to undermine critics' concerns about the product (Abraham and Sheppard 1999; Healy 2004). Thus, the industry's creation of assimilated allies in the medical/science professions helps to protect pharmaceuticalization from countervailing powers. For example, internal memos of the pharmaceutical manufacturer Upjohn released in open court revealed that the company was willing to use what the judge called "cut-throat commercial tactics" to prevent doctors such as van der Kroef and Oswald, mentioned below, from publicizing concerns about the dangers posed by Halcion:

> We [Upjohn] must stop further publication by van der Kroef in major journals. . . . We must learn everything possible about van der Kroef, and be prepared to use the evidence. It should be clear that someone is going to get hurt and this is going to be a long and tough battle. . . .

5. Off-label use is the prescription of a drug for indications ("conditions") for which it was not licensed.

> Oswald paper indicated high percentage of Halcion users have problems. So far we have been successful in having it [publication of the paper] stopped. (passages from Abraham 2002: 1677, 1679, 1684)

Sometimes pharmaceuticalization and medicalization go hand in hand. For example, doctors' prescribing of pharmaceuticals may increase because of widening diagnostic criteria of conditions for which new drugs are emerging or for which existing drugs may be "repackaged" for a new market (Conrad and Potter 2000). This phenomenon has been reinforced by the 2000 NHS Plan, which envisaged the involvement of the pharmaceutical industry in NHS "disease management" via "national service frameworks," including protocols for drug therapies for particular conditions (Pollock 2004: 66). Such medicalization by the psychiatry profession partly explains why, between 1993 and 2002, NHS prescriptions in England for SSRIs to treat depression grew from 1,884,571 to 15,500,000, and for Ritalin to treat attention deficit hyperactivity disorder (ADHD) grew from 3,500 to 161,800 (American Psychiatric Association 1994; DoH 1994b, 2003). Supporters of such pharmaceuticalization argue that it reflects advances in medical science that enable treatment for people diagnosed with ADHD and depression who would previously have gone undiagnosed (Castellanos et al. 2002; Harding 2001). From this perspective, pharmaceuticalization simply corresponds to the increasingly sensitive means of detecting the biological bases for illness. However, research from social science suggests that pharmaceuticalization, including industry-sponsored "disease awareness campaigns" aimed at doctors and patients via expert opinion leaders, has exaggerated the benefits and neglected serious adverse effects of tranquilizers (in the 1970s and 1980s) and antidepressants (since the early 1990s), especially problems of addiction and dependence (Abraham and Sheppard 1999; Gabe 1991; Healy 2004; HCHC 2005: 69–70; Medawar, Rassaby, and Guthrie 1992; Medawar and Hardon 2004).

Alongside the growth in pharmaceuticalization, rising "consumerism" has emerged, characterized by greater reflexivity, expertise, and/or activism among NHS patients. Two forms of consumerism are pertinent to the governance of the pharmaceutical industry and the NHS: injury-oriented adversary and access-oriented collaboration with the medical-industrial complex. In the late 1980s, NHS patients embarked on extensive legal actions against Eli Lilly and the U.K. drug regulators, following injuries associated with the arthritis drug Opren. Similarly, in the early 1990s large-scale legal action was taken by patients against the manufacturers of

benzodiazepines; a BBC TV *Panorama* documentary broadcast patients and medical experts attacking Upjohn (the manufacturer) for its handling of safety problems with Halcion. However, the countervailing powers of injury-oriented adversarial consumerism against major pharmaceutical companies in the United Kingdom have had very limited success. The Opren litigation dissipated into a low-cost out-of-court settlement offered by the company, with no blame attached to either the manufacturer or the regulators, and the legal action against benzodiazepine manufacturers collapsed, leaving many users of the drugs still without compensation, while Upjohn won a major libel action against the BBC regarding its documentary on Halcion (Abraham 1994a; Abraham and Sheppard 1999; HCHC 2005: 65–66).

By contrast, access-oriented collaborative consumerism has enjoyed considerable victories in *alliance* with pharmaceutical firms. The governance of beta interferon treatment stands as but one example of patient groups successfully challenging local government and NICE. Although NICE recommended use of the drug Herceptin on the NHS for advanced breast cancer in March 2002, there was no such advice for its use to treat early-stage breast cancer. Indeed, at that time the manufacturer, Roche, had not even submitted data to the MHRA in support of a licensing application to have the drug approved for such use in the United Kingdom. However, in May 2005, a U.S. trial of the drug with women suffering from early-stage breast cancer reported promising results. A few months later, when a woman with early-stage breast cancer in Stoke-on-Trent was refused Herceptin on the NHS, she threatened litigation in the national media. In October 2005, Secretary of State for Health Patricia Hewitt responded by stating on national television that all breast cancer sufferers should have access to the drug, even though Roche had still not made a licencing application for full regulatory review of Herceptin for such use. After Hewitt's intervention, the NHS reversed its decision, obviating the need for a very public court case. However, when the NHS withheld Herceptin from another woman with early-stage breast cancer, its decision was overruled in a high-profile court case in April 2006 (Woman Wins Herceptin Court Fight 2006). In June 2006, after Herceptin had been licensed for treatment of early-stage breast cancer by the MHRA, NICE speedily recommended it for such use on the NHS under a cloud of suspicion that it had been rushed into doing so by patient pressure on the DoH (Berg 2006).

Further evidence of the significance of access-oriented patient activism may be observed regarding drugs for Alzheimer's disease. In March 2005,

NICE recommended that four drug treatments licensed for Alzheimer's (Aricept, Exelon, Reminyl, and Ebixa) should not be funded by the NHS because they were not cost-effective. However, following a high-profile campaign in the media and a formal appeal involving patient groups such as the Alzheimer's Society, NICE revised its guidance to allow NHS funding of the drugs for people with moderate stages of the disease but still not those with early-stage Alzheimer's. The Alzheimer's Society then took NICE to the courts, which initially supported NICE's revised recommendation but subsequently insisted that NICE should investigate ways of making the drugs available to all those with the disease (Alzheimer's Drugs Remain Limited 2007).

All these successful cases of consumer activism have involved patient groups seeking access to drugs, in alliance with pharmaceutical manufacturers. In the case of Herceptin, the activism itself may have been marshaled by Roche. After publication of the promising U.S. trial, Roche hired a public relations firm to contact some women in the United Kingdom with breast cancer to ask them if they would be willing to help to get the drug funded on the NHS before NICE, or even MHRA, approval (Berg 2006). Regarding the campaign for access to Alzheimer's drugs, the manufacturers were the lead claimants in the court case and centrally involved in the formal appeal to NICE—as also occurred with the MS Society campaign for access to beta interferon (Alzheimer's Drugs Remain Limited 2007). The evidence suggests that the apparent power of patient activism to challenge the medical expertise of the state may significantly depend on whether it is supporting or contravening the fundamental interests of the pharmaceutical industry. According to Crinson (2004: 40), the main reason the DoH ensured patient access to beta interferon was "to avoid a direct confrontation with the drug manufacturers."

This phenomenon is likely to become a permanent feature of the pharmaceutical governance landscape because many patient organizations that campaign for availability of better treatments for various medical conditions have not only formed alliances with drug manufacturers when tactically advantageous but, in the last decade, have become increasingly *funded* by pharmaceutical companies (O'Donovan 2007). While the precise effects of pharmaceutical firms' financial support on patient groups is difficult to gauge, such close associations are clearly important to the industry as an additional pathway, beyond doctors, for creating consumer demand for their products (Herxheimer 2003). In a survey of U.S. executives from fourteen pharmaceutical companies, 75 percent of respondents cited "patient education" as the top-ranked marketing activity necessary

to bring a brand to "the number one spot" (HCHC 2005: 74–76). Thus, sometimes unwittingly, pharmaceuticalization and consumerism, which have emerged since the 1980s, appear to be significant allies of corporate bias and have continued to undermine some elements of the state's countervailing agendas of rationalization and cost-effectiveness for the NHS.

A vivid example of how the complex interaction between pharmaceuticalization and consumerism can shape U.K. health policy considerations is the debate about "patient education" and direct-to-consumer advertising (DTCA) of prescription drugs. In the EU (and hence United Kingdom), pharmaceutical companies are not allowed to advertise/promote their prescription medicinal products directly to NHS patients or the general public, though from 2009 they might be permitted to provide some information about their products directly to consumers via some media. During the last decade, the industry, with support from the European Commission, has campaigned vigorously, but so far unsuccessfully, for the complete legalization of direct-to-consumer advertising of prescription drugs. This campaign has characterized patients as consumers able to decide which drugs are best for them without doctors as gatekeepers. It has utilized a discourse of the "informed patient" and the "expert patient," terminology that was subsequently adopted uncritically by the DoH (2001).

For some social scientists, such discourse can be accepted at face value, casting the debate about DTCA in terms of empowerment of lay patients versus expert "medical dominance" (Fox, Ward, and Rourke 2005). Doctors' failure to adequately inform NHS patients about prescription medicines is a significant problem (Britten 2008). However, it is a considerable leap of faith to embrace a policy based on the assumption that pharmaceutical companies will fill the gap left by doctors in this respect. That assumption lacks any analysis of the interests involved and, remarkably, ignores the evidence of widespread problems for patients' health and NHS resources posed by misleading advertisements to doctors, let alone patients — evidence that, as I have noted, stretches back to the 1950s. Social science analyses embracing the discourse of "expert patient" also tend to ignore the evidence from the United States (where DTCA is legal) about its many drawbacks, reported as early as 1984 in congressional investigations (U.S. Congress 1984).

The "expert patient" discourse needs to be put in its proper political context by relating it to the interests of those planning to provide the information intended to construct "patient expertise" and the ideological nature of its emergence. Quoting from a speech by the director general of the ABPI, Medawar and Hardon (2004: 121) report that the 1998 "Informed

Patient Initiative" was the first part of the industry's "battle plan," while the second part was the ABPI's publication "The Expert Patient," which, according to the director general, was "part of a softening-up assault to be mounted through those interested parties and opinion leaders by stimulating debate." Evidently, the purpose of the campaign was to promote a consumerist ideology of patient self-care and self-medication in order to create a basis for arguing that patients are sufficiently knowledgeable to evaluate advertising claims about powerful prescription drugs. As the following passage from an article published in *Pharmaceutical Marketing* suggests, the industry hoped that the creation of such consumerist ideology and concomitant assimilated allies would be sufficient to compel European regulators and governments to legalize DTCA for EU, and hence NHS, patients: "The ABPI battle plan is to employ ground troops in the form of patient support groups, sympathetic medical opinion and healthcare professionals which will lead the debate on the informed patient issue. This will have the effect of weakening political, ideological and professional defences. . . . Then the ABPI will follow through with high-level precision strikes on specific regulatory enclaves in both Whitehall and Brussels" (Jeffries 2000, quoted in Medawar and Hardon 2005: 121).

To date, the European Parliament, the key countervailing power against the corporate bias of the industry and the European Commission, has refused complete legalization of DTCA. It has concluded that it would not be in the interests of patients' health. Nevertheless, the consumerist ideology surrounding the campaign left its mark on the European Commission and U.K. pharmaceutical policy frameworks for the NHS. For example, after consultation with the pharmaceutical industry and following the extensive opposition to complete legalization of DTCA, the European Commission proposed new legislation in 2008 that would maintain the general ban on DTCA but would allow industry to provide "additional information" to the public via the media (Richards 2008). Other countervailing forces, such as EU public health organizations, medical professionals, and some national government health agencies, have opposed relaxation of the ban, underlining the crucial role of health professionals in the provision of tailored information to patients. Meanwhile, critics have argued that the commission proposal, which is supported by the pharmaceutical industry, is in effect a legalization of DTCA because of the practical difficulties of regulating and enforcing the distinction between "information" and "advertisement" (Association Internationale de al Mutualite et al. 2008). Yet the MHRA and the NHS view the proposal as "broadly acceptable" because they share the ideological perspective that there is an

"information gap" that pharmaceutical companies are needed to fill for patients (MHRA 2008: 28–29). It remains to be seen whether the industry's success in assimilating allies at the European Commission, the DoH, and the MHRA will be sufficient to overcome the countervailing powers in the European Parliament and health professions against any relaxation of the ban on DTCA.

Furthermore, the U.K. government and the pharmaceutical industry agreed in 2004 to double the number of drugs to be reclassified from prescription-only medicine (POM) to over-the-counter (OTC) status annually (HCHC 2005: 88–89). This consumerist policy originated from the corporate bias of a state-industry partnership, not patients or consumers. The initial recommendation came from the Pharmaceutical Industry Competitiveness Task Force (PICTF), which was formed in 2000 with equal representation from government and industry and whose overall aim was to ensure that the United Kingdom was an attractive location for the pharmaceutical industry. In effect, this policy accelerated the pace at which NHS patients could be turned into "retail" consumers by bypassing the need to use the NHS, with respect to pharmaceutical consumption. It was in the interests of the state because OTC medicines are not reimbursed by the NHS; they are out-of-pocket private consumer purchases. Simultaneously, pharmaceutical manufacturers could market more of their products directly to consumers (former NHS patients) because there was never a ban on DTCA for OTC drugs. For consumers/patients, availability of these drugs became more convenient, as a visit to the doctor was no longer necessary. On the other hand, guidance on their use from a medical professional declined, as did NHS subsidization of their costs for users.

Conclusion

The pharmaceutical industry, drug regulators, health policy makers, and NHS professionals and managers all agree, publicly at least, that the fundamental purpose of pharmaceuticals is to improve health and health care for patients and the wider public. The NHS was also founded by the British state with the same purpose. Of course, in practice, other factors, such as commercial and professional interests, have clashed with that basic, declared objective. Nevertheless, it remains the best standard against which to reflect on how well the governance of the pharmaceutical industry and the NHS has fared in the last sixty years. I suggest that one's overall assessment depends on the focus and emphasis taken, so I will

conclude by offering an optimistic view that appreciates the indisputable progress that has been made, tempered by a pessimistic one that notes the restricted nature of that progress and some outstanding challenges yet to be met.

The optimistic view is that health policy in this field has come a long way since 1948. The safety and efficacy of pharmaceuticals are now subjected to government regulatory review, and all NHS drugs have met or surpassed modern standards of efficacy. The expert advisers to government involved in such regulatory review are no longer permitted to have direct financial interests, such as shares, in pharmaceutical companies, which probably makes for more robust regulation. There is now a considerable body of state-funded scientific methodology and expertise from which the NHS can draw in order to make judgments about whether specific drugs are cost-effective for the Health Service, especially since the establishment of NICE in 1999. Rational prescribing is a much more accepted norm than before among NHS medical professionals, some of whom have become more proactive in discerning misleading drug company promotion. In these respects, a number of the undesirable aspects of corporate bias have been successfully counteracted or compensated for. Consequently, the NHS tends to have much safer and more effective drugs made available to it, and it can make more efficient use of the new drugs available than it could in the 1950s and 1960s. In particular, the pharmaceutical industry has developed drugs for treating HIV/AIDS, Alzheimer's disease, MS, cancer, and high blood pressure that have been beneficial to some NHS patients.

On the other hand, there has been little or no progress in reforming the regulation of drug pricing, despite numerous official reports demonstrating that it is not in the interests of the NHS. Furthermore, drug safety and efficacy regulation for NHS patients was a long time in coming and has had rather limited ambitions at each stage of development. It is staggering that even after a major drug disaster in the 1960s, the government took nearly ten years to implement legally enforceable safety regulation with formal regulatory authorities. In the United States and Scandinavia, drug safety regulation predated the NHS, beginning in the 1920s and 1930s, but came to the United Kingdom twenty-three years into the life of the NHS. That implementation has too often lacked sufficient stringency to protect NHS patients, while efficacy regulations did not require pharmaceutical manufacturers to demonstrate that their products were more therapeutically effective than drugs already on the market. It took another thirty years before the British government introduced a nationally based

system of assessing the effectiveness of new drugs compared with existing pharmaceuticals, but even this is only in relation to the financial cost to the NHS in the postlicensing phase. To this day, there are no preapproval comparative efficacy regulatory standards that could steer pharmaceutical innovation toward the development of drugs that must provide significant therapeutic advance.

The foregoing analysis suggests that the principal reason for such slow progress and limited health policy ambitions in the governance of pharmaceutical safety, efficacy, and pricing has been extensive influence of the pharmaceutical industry over policy development, implementation, and interpretation. In this respect, the British state's dealings with the pharmaceutical industry have not served the NHS and its patients well. Due to corporate bias and the relative absence of countervailing powers, regulation of drug safety, efficacy, and pricing have been consistently weak, sluggish, and subject to repeated cycles of crisis or disaster due to an apparent incapacity to learn lessons from the past and reform. This is why, during a period of about half a century, the state has failed to protect NHS patients from "subsequent thalidomides," such as Practolol, Opren, and Vioxx, and has also failed to insist that pharmaceutical prices for the NHS be linked to therapeutic value. It is also partly why the last sixty years has seen a proliferation of "me-too" drugs that offer little or no therapeutic advance—indeed, the large majority of new drugs fall into that category (Lexchin 2006). Moreover, in the last fifteen years the number of new drugs offering significant therapeutic advance has been in decline.

The state has asserted its own interests in efficient use of NHS resources for drug prescribing, most notably via NICE's cost-effectiveness assessments. These are substantial steps forward in governing pharmaceuticals in the interests of health and health care. However, they face major new challenges, as well as the traditional concerns of the medical profession about protection of their clinical autonomy. Perhaps more significant for health policy in this field than threats to medical expertise and clinical autonomy is the industry's creation of assimilated allies with an ideological assault on the consciousness of the medical profession, promoting pharmaceuticalization in the NHS and affecting what physicians learn about diagnostic criteria, what they are told by opinion leaders in continuing medical "education," what they conclude from biased medical journal articles, and what they absorb from sales representatives and advertisements. Not all pharmaceuticalization is contrary to the interests of health or the NHS, but some of it can be. The assault is so pervasive that it may be difficult for busy NHS physicians to distinguish ideology about phar-

maceuticals from valid knowledge — all the more so if their patients are demanding particular drugs because they are being recommended on the Web sites of industry-funded patient organizations. While the consumerist discourse of the "informed/expert patient" may be well advanced in the NHS, provisions for real public accountability of pharmaceutical development and regulation remain very poor in a U.K. government-industry complex shrouded in secrecy and a regulatory system whose public rights of access to information lag behind many other regimes, such as the United States, Sweden, and the supranational EU.

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