There is growing disquiet over market incursions into the arena of health delivery and the transformation of health care into a commodity. The global health industry at the centre of this has become increasingly visible, raising critical questions about the structural integrity and survival of health systems everywhere.¹

Despite these palpable concerns, capturing an image of the private health industry as a whole is as overwhelming as it is complicated. It is difficult to determine which social processes should or should not be included, and the blurred lines between public activity and private accumulation make strict identifications of the industry near impossible. By way of example, private social insurance funds can be non-profit, with a clear public interest, but can also be amenable to being converted into internal markets and, ultimately, entering into for-profit competition. Still, it is important not only to try to map the most important elements of this industry, but also to consider its politico-economic strategies in relation to existing public-private health system configurations.

This essay contends that the health industry, while undoubtedly encouraging a uniform trend toward private accumulation of 'wealth in health', settles for pragmatic strategies of institutional adaptation that optimise its returns within existing political conditions. To the degree that expanding accumulation meets with blockages, commercial health 'providers', in particular, seek ways of harnessing prevailing political and institutional arrangements towards their most profitable ends.

Compelling Accumulation

The health industry can be understood as a chain of accumulation processes, from health research through to service delivery, but it proves no easy task to capture these processes conceptually. The task is further complicated by the fact that 'diversity' across regions undermines homogeneous accounts of the capitalist world, meaning that any useful conceptual representation of this industry must incorporate the lessons of comparative political economy. It must, in other words, struggle with the reality that... capitalist development is driven by encompassing competitive imperatives to adapt to the world market and the laws of accumulation, but it is also always differentiated by particular strategies of social actors, mediating institutions, and political conflicts'.² While it would be virtually impossible to enumerate in concrete detail the many specificities of the health industry, establishing its general tendencies is not beyond our grasp.

In this vein, the Hayekian accumulation regime that accompanied the rise of Thatcher and Reagan included a far wider conception of what counts as justifiable terrain for private profit-taking. As Richard Peet has pointed out, the onslaught of neoliberalism signalled more than just the re-adoption of unbridled liberalism - it also connoted an outright disdain for all things associated with the Keynesian state;³ and the provision of health care via public channels was included among the domains targeted for dismantling, dismemberment or transformation. David Harvey's conception of 'accumulation by dispossession' captures this phenomenon as one in which hitherto existing forms association, organisation, identity and creativity are forcibly channelled into the private domain, so that value can be either siphoned off or extracted anew. In fact, in relation to health, Harvey goes so far as to say that 'the reversion of common property rights won through years of hard class struggle (the right to state pension, to welfare, to national health care) to the private domain has been one of the most egregious of all policies of dispossession pursued in the name of neo-liberal orthodoxy'.⁴ There is a strong sense in which Harvey's formulation successfully captures the objectives and accomplishments of the health industry. Robust, commercially-driven research agendas; ongoing spectacular profit levels in health-related corporations; and a worldwide drive to
open health delivery to private channels; all imply a forceful sweeping-up of common achievements
during (especially) the post-Second-World-War period.

We can, to be sure, emphasise a feature of all parts of the health industry — the drive to
accumulate. In keeping with the neoliberal turn, the industry exhibits an almost unquenchable thirst
for better than average and, often, extraordinary profits. While always seeking political shelter from
the vicissitudes of capitalist competition, the industry’s various segments nevertheless evince a
compulsion to maximise returns within a widespread shareholder culture that has come to ‘bet on'
health as a lead sector in the (falsey advertised) ‘new economy’. Health represents a domain in
which the maximisation of returns appears limitless. There is neither a ceiling for how healthy
societies should be, nor a shortage of medical conditions — real or contrived — that require
diagnosis and (preferably prolonged) treatment. Health, moreover, surely must be seen as a basic
human need, and is often even portrayed as a right. As such, what I have elsewhere called the
production-provision-profit dynamic of the health industry occurs in a sectoral environment that is
politically unique. The various components of the health industry enjoy the luxury of self-identifying
as social actors who are first and foremost in the business of meeting human needs, obscuring the
reality of their enormous returns on investment and being able to represent these, when they are
noticed, as being of secondary importance. Who, after all, can be against the pursuit of health?

There is, however, also a sense in which ‘accumulation by dispossession’ does not capture the
subtle actions of the health industry. In its various guises, it is never the case that the industry
necessarily seeks out systemic transformation along privatised lines. Precisely because health
constitutes a terrain that is politically unique, it is also a sensitive one for which different societies
exhibit varying degrees of entitlement and protectiveness with regard to publicly-arranged social
programmes. While the extension and growth of the productive and service elements of the health
industry has undoubtedly gone far, the degree to which this involves dispossession varies across
time and geography. Processes of privatisation and corporatisation can meet bitter resistance in
relation to health, and, as a result, the health industry manoeuvres very carefully when trying to
assure or extend its avenues of accumulation. This side of the sector is better captured by the idea
of accumulation by institutional adaptation, wherein the industry seeks to optimise its operating
environment, given current and probable future circumstances. Here, institutional specificities
cannot be sidestepped. As Greg Albo has put it:

[T]he agencies of capitalist social relations act through, are constrained by, and
transform institutions. Institutions are, in a very real sense, the crystallization of power
relations and class struggles of specific social formations; but institutional social forms are
not reducible to class relations as their very materiality in terms of rules, norms and
resources are quite distinct from class actors themselves. This conception carries two
important implications. The social structures and economic imperatives that constrain and
condition social agents are the unintended results of these same social agents acting
through institutions ... And although social agents are embedded in institutional contexts,
their conflicting strategies for reproduction continually transform and reorder these
institutions.5

Such institutional ‘crystallisations’ cannot be over-emphasised in relation to the health industry,
because state and quasi-public organisations play sizeable intermediary roles in many aspects of
the sector.

Adaptation means enabling an environment in which agents of the health industry can gain the
most from existing institutional parameters, as they change over time. In instances where market
competition — or some reasonable facsimile — is the objective, dismemberment or dissolution of
(particularly state) institutional control over specific health spheres becomes the order of the day.
However, it need not always imply erosion or dissolution of institutional formations. In fact, it can
very well mean the maintenance or even expansion of these formations, particularly if the
prevailing political environment ensures that the industry's best strategy is to harness existing
arrangements to their advantage. This is not to say that the health industry remains passive in the
face of institutional rigidities or political caprice. On the contrary, struggles are engaged in regularly
on its behalf (whether by companies or, more likely, trade associations) which seek to defend or enhance private accumulation. But this remains a rather meticulous and vigilant game of 'thrust and parry', wherein agents of the industry realise that consolidating routes to accumulation can take counter-intuitive pathways. Ostensibly non-commodified mechanisms can be encouraged, because they offer the most plausible means to foster the best returns to the industry.

This pragmatism requires an attentive and ever-ready industry, prepared and able to intervene in every crevice of the institutional environment. As the industry relies heavily on the stability afforded by this environment, very little is left to political chance. Corporations, trade associations, societies for the treatment of myriad medical conditions (such as the Heart and Stroke Foundation or the American Cancer Society), and public institutions receiving substantial private funding (such as Tufts University or Scripps Medical Centre) all stand ready to advocate the interests of various parts of the industry, in order either to prevent damage to accumulation streams or strategically redesign them. To the greatest degree possible, the industry fights to firewall itself from the debilitating effects of market competition. This is not altogether surprising in any industrial sector, but the remarkable success of pragmatic institutional strategies within health place it atop the list of dynamic sectors in contemporary capitalism.

The Industrial Core of Health

At the heart of accumulation by institutional adaptation stands a multifaceted health industry that remains, even through recessionary periods, highly profitable. However, while health may appear unique in its potential for unbounded commodification, there is nothing inevitable about the exploding growth witnessed in this sector over the last three decades. While the industry is subject to much evaluation on a national scale, with some cross-country comparisons in health care or the pharmaceutical industry, on a global scale data simply do not exist. That said, we can rest assured that the industry is gargantuan in scale and growing. In the United States alone, health spending — both private and public — is projected by 2014 to be in the range of $3.5 trillion, constituting 18.7 per cent of US GDP. This represents a spectacular climb from $888 billion, or 13.4 per cent of GDP, in 1993. And although the United States is the most vigorous market for health spending, it is followed by other growing markets, predominantly in the OECD. While worldwide health spending reached $4.5 trillion in 2006, $2 trillion was accounted for by the United States, while another $2.2 trillion came from other OECD countries. This upward spending dynamic now regularly gets chalked up to (i.e. blamed on) ageing populations in the advanced industrial states, but the slow and steady growth of the latter cannot plausibly account for explosive growth in accumulation.

Rather than seeing this industry's fortunes as a mere response to populations' 'natural' demands, it is the health industry's self-expanding accumulation strategies that must be examined as candidates for the prime movers of growth. This rightfully begins with mention of research-related industrial activity, a phenomenon fostered by competitive growth strategies on the part of many states. At the centre of this frenzy has been the pharmaceutical industry, with its encompassing drive to extract value (real or imagined) from every possible source. As pharmaceutical profits took off in the early 1980s, much of it occurred in the guise of an innovation-led 'biotechnology revolution' — a 'revolution' which has, in turn, laid the basis for new industry claims to be enhancing health outcomes. The fact that biotechnology's rise was closely linked to pharmaceutical funding and business development finds virtually no recognition among industrial or academic commentators. But the reality is something different, as Koyin Chang has rightly pointed out:

Most NBFs [new biotechnology firms] have relied on other established firms for investments. The role of established enterprises as investors in NBFs is suggested by the fact that between 1976 and 1985, they provided 56 percent of the total funds invested in NBFs. [The] dependence of NBFs on corporate partners is further illustrated by considering the role of contract R&D for two of the oldest and largest NBFs: Genentech and Cetus. Revenues from development contracts funded 70 percent of Genentech's total R&D
between 1976 and 1980. Contract R&D undertaken by Cetus accounted for 65 percent of its total R&D expenditures in 1981 ... Although not the intention of the NBF founders, the biotechnology industry, in its early years, took on the characteristics of a specialised R&D supply sector. Indeed, it could be argued that the biotechnology industry emerged as a market for R&D, with NBFs on the supply side and established chemical and pharmaceutical enterprises on the demand side. 10

This is not to say that there was never 'entrepreneurship' chasing venture capital, but this cannot be characterised — then or now — as biotechnology's prime mover. Instead, leading pharmaceutical firms, facing a severe drought of patent-protected products, ensured the launch of myriad research-driven small firms (and continue to bolster them today) in order to fill a void in upcoming commodities that could be promoted as innovative.

Naturally, such a depiction of events runs counter to the claims of the newly minted 'biopharmaceutical' sector, where bountiful discoveries are said to be key to tomorrow's health. Indeed, the Pharmaceutical and Research Manufacturers of America (PhRMA) claims that research and development (R&D) in life-saving medicines reached an astounding $65.2 billion in 2008, despite the downward economic pressures. 11 Used to justify extraordinary mark-ups in drug pricing, such R&D claims (along with a host of other claims) have been severely taken to task by critics. 12 It is very unlikely, for instance, that the costs of developing successful drugs are anywhere near the numbers declared by industry, which are mostly accepted at face value in governmental, academic and popular circles. Probably more insidious is the fact, in tune with the PDA's own regulatory reporting standards, that only a small fraction of biopharmaceutical products can be characterised as anything akin to innovative. 13 It is, however, precisely along these lines that the industry makes its most emphatic pleas for societal legitimacy and industrial support.

In the context of this investment hype, industrial advocates pursue a politically sophisticated strategy for institutional adaptation in ways that glorify their putative market objectives, all the while pursuing relative shelter from the market. The entire endeavour to save lives is subjected to a bottom line by biopharmaceutical spokespeople, holding for ransom the perceived future well-being of populations. Billy Tauzin, the CEO of PhRMA, consistently reiterates an oft-heard call from the biomedical industry: 'in order to foster these much-needed medical breakthroughs, we must continue to pursue public policies that provide... [an] opportunity to recoup and secure the benefits of their significant investments'. 14 The Biotechnology Industry Organization (BIO) echoes this by asserting that '[b]iotechnology product development is also fraught with high risk, and the vast majority of experimental biotech products fail to ever reach the marketplace. Investors will invest in capital-intensive, long-term, and high-risk research and development endeavours only if they believe there will be a return on their investment'. 15 Importantly, this rationalisation of extraordinary market returns rarely brings with it an environment of extreme investment risk, with which biopharmaceutical protagonists always fend off critics. The extent to which these same firms seek a 'free market' remains strictly limited; accompanying the quest for remarkable profits is an equally strong imperative to control structures and procedures which affect the industry's unique context.

This means, first and foremost, ensuring that public budgets are heavily tapped to provide the infrastructures needed for biomedical development. Infrastructural outlay is the first condition for an increasingly expanding biomedical sphere, dependent on a vast array of information-based (as distinct from innovative) production. In this case, accumulation by institutional adaptation manifests itself in the constant incorporation of publicly-financed spheres of R&D as a way both to force open access to mental labour and to defray corporate investment costs.

The biopharmaceutical sector forms the archetype, where the rash to capitalise on decades of research stemming from biotech firms, university laboratories and public research could not be more evident — witness the flurry of public-private contracts with the National Institutes of Health (NIH); gargantuan funding agreements between pharmaceutical and biotech firms; and waves of takeovers, buyouts, alliances and mergers. Within the US, the desire to keep feeding research with funding to back this public-private configuration continues to grow; NIH-backed research exceeded a remarkable $29 billion in 2008. 16 Even the otherwise distracted Bush Administration encouraged and endorsed a doubling of the funding for the NIH. 17 Previous to this, of course, Congress and
several administrations went out of their way to validate and underwrite the execution of the Human Genome Project, an infrastructural endeavour to provide genetic cartography for the highly expectant biotechnology and pharmaceutical industries.\footnote{The next round of support has long since started with the progressive exploration of proteomics, an attempt to map out the vastly complex terrain of the human protein complement.}

This is hardly confined to the United States, as competitive strategies on the part of industrial states abound in the arena of biopharmaceutical development. The newest and fastest growing competitor in the European context, Germany, recognised (albeit somewhat late) the potential returns to a refurbished health industry. In relation to biotechnology, the government's air of desperation suggests that the industry is, '... a decisive touchstone as to whether Germany will capture a leading international position, pushing forward in innovative fields of the future, which open new employment opportunities'.\footnote{The degree to which the future of economies like Germany's is seen as dependent on the expansion of health industrial possibilities could not be more marked. Germany's creation of the 'BioRegio' contest (a publicly-financed attempt to create four regional biomedical clusters) helped to usher in a new era of governmental assistance for biopharmaceutical research and development.\footnote{This story, of course, can be repeated for a large array of OECD and non-OECD competitors, including (but not limited to) Canada, the United Kingdom, France and India. Each programme depends on a specific and carefully balanced configuration of accumulation imperatives and socially distributed risk. In the end, biopharmaceutical capital relies on an \textit{optimal} evasion of market principles to acquire the mental commodities that it either fails to generate or cannot afford on its own.}}

Just as the pursuit of 'wealth in health' cannot be confined geographically (even if its epicentre is the United States), it should also not be seen as solely attributable to biopharmaceutical actors. Other sectors seek to intensify the need for health products, not the least of which is biomedical instrumentation, including diagnostics. This industrial sector, represented most forcefully by the Advanced Medical Technology Association (AdvaMed), seeks both industrial protection (via patents) and systems of health care delivery that endorse leading-edge medical procedures and the burgeoning use of diagnostic tests.\footnote{The industry's revenues for 2007 were hardly trifling, at $180 billion, a 6.4 per cent increase over the previous year.\footnote{Moreover, the sector echoes the growing refrain of the wider health industry — that intense research and development constitutes its most important driver of success. The push for constantly enhanced biomedical instrumentation, and — more ominously — diagnostics, represents a strong contribution to the push for a rate of industrial growth that probably far exceeds any reasonable measure of patient 'need'.}}

AdvaMed, in fact, takes an aggressive stance vis-a-vis the opportunities to expand the utilisation of medical technologies through US trade mechanisms. Like PhRMA, it interacts with the US Trade Representative and Congress (USTR) to save more lives abroad:

\begin{quote}
AdvaMed believes the USTR, Department of Commerce and Congress should monitor regulatory, technology assessment and reimbursement policies in foreign health care systems and push for the creation or maintenance of transparent assessment processes and the opportunity for industry participation in decision making. We look to the Administration and Congress to actively oppose excessive regulation, government price controls, foreign reference pricing schemes, and arbitrary, across-the-board reimbursement cuts imposed on foreign medical devices and diagnostics.\footnote{The industry zeros in on a range of OECD and non-OECD markets, with an eye to ridding its potential sales markets of 'unnecessary' regulation and reimbursement regimes. It decries cost control measures in Brazil, India and China, insisting in the case of the last of these that health care be included in the Strategic Economic Dialogue. Opening up such markets is certainly in the interest of AdvaMed member firms, but the real targets are still the OECD's healthcare systems, where the 'barrier' is constituted by efforts to control lucrative public spending. The industry urges the USTR to pursue EU countries (particularly Germany and France) on the issue of reimbursement and health technology assessment, insisting that each should match practice in the United States. The industry makes the claim that '[b]reakthrough products available in the United}
States to a majority of patients are still available to only a small fraction of eligible patients in the major European markets.

More likely than unavailable, such technologies are, from the perspective of industry, simply under-purchased. Indeed, AdvaMed reveals its deeper anxieties concerning under-spending in the case of Japan, protesting the fact that the second largest healthcare market after the United States also has the lowest percentage of GDP spent on health. Here is the essence of the health industry's strategy of institutional adaptation: to the degree that exceptional spending levels within health economies can be encouraged, provider industries seek to enhance their exposure to this spending through whatever mechanism is both lucrative and politically expedient.

This brings us to the pressure point of the entire health industry: healthcare delivery. Configurations of healthcare delivery vary enormously and in response to this fact the health industry consistently makes a virtue out of necessity, operating in a shifting terrain of private and public venues, where spending is, to the greatest degree possible, always 'optimised' in capital's favour. But this optimisation of spending is deeply intertwined with political realities, including a widespread extra-economic attachment by local populations to the institutions that provide healthcare. This is why the specific forms these institutions take constitute the industry's most serious strategic concern. As investment in biomedical and biopharmaceutical research, design and development intensifies, and an increasing number of saleable health commodities (in both products and procedures), meet with the different manifestations of rationing, reimbursement and economisation that are inherent in healthcare delivery. Because of this, choices about how many private channels are to be involved in health care matter less in relation to 'efficiency' (as reform advocates insist) and far more in terms expandable accumulation opportunities.

The epicentre of private health care is, again, the United States, with a highly developed — and exceptionally complicated — market in healthcare financing and provision. While a substantial portion of the American population receive either Medicare or Medicaid benefits, the vast majority have their health care arranged through some form of managed care organisation or health maintenance organisation (HMO). The dynamic strength of US private health delivery should not be underestimated, and the manner in which Medicare and Medicaid consistently endure, albeit on the edge of systemic survivability, is a very strong indication of this fact. As Jacob Hacker has pointed out:

By taking the most costly and difficult-to-insure populations out of the private insurance system, Medicare and Medicaid at once strengthened private insurance and removed much of the remaining political pressure for reform. This was not the only reason that proposals for universal health insurance failed in the 1970s and 1990s, but it did contribute to these political defeats and, more subtly, to a continuing transformation of the goals of reformers.

US per capita health spending is now over $6,000, roughly double that of most other OECD countries. That so much is spent on health might make it surprising that over 47 million Americans have no health insurance, if it were not for the fact that private actors underwrite the majority of coverage. US health insurers have clearly opted to exclude the most vulnerable portions of the population and keep their prices high, rather than expand their market and have to set premium-reducing precedents for low-income patients. Related to this, in a market where purchasers of services and products are parcelled out, and a competitive marketplace in health is celebrated, any serious possibility of system-wide cost leverage held by financers/purchasers over providers is largely relinquished. Purchasers may be able to get costs lowered on a firm-to-firm basis, either through securing discounts on procedures or products purchased in sufficient volume or through policing individual benefits. However this has very little to do with system-wide forms of cost-containment, as there is no agent with enough leverage either to lower dramatically the costs of provision or to impose universal decisions about which treatments and/or products are medically necessary. Add to this the fact that purchasers must compete for segments of the population for whom refusal to cover the 'innovative' care is not good advertising. Market competition leads to a progressively more open-ended set of transaction possibilities, in a political context in which there
is no universal regulation of allowable treatments, prescriptions, price or reimbursement. As a result the politically-constituted prices of biomedical and biopharmaceutical industries are protected. A divided health care system is able to control costs only on an individual basis, patient by patient — or, more appropriately, consumer by consumer.

The particular blend of public and private healthcare provision in the United States has been in keeping with an ensemble of state policies and structures typically subordinated to market-oriented civil society. Considerable amounts of public revenue devoted to health structures are carefully routed through for-profit channels. Given the runaway costs, it would seem a logical move for policy-makers to grasp at control by turning to a publicly-oriented reorganisation of health. However, certain matters are taboo in US health politics, chief among them the issue of 'price'. In relation to the biopharmaceutical sector and health care, Sherrod Brown has appealed to congressional colleagues to reconsider their overly favourable attitude to the industry:

[We] jump when the drug industry says jump, and whether its pediatric exclusivity, whether its PDUFA [see below], whether it's a whole host of issues. It rushes to pass legislation when the drug industry wants us to pass legislation ... This industry knows that 70 million Americans, many of them seniors, have no coverage for drugs. The uninsured have the distinction of paying the highest prices in the world with no insurance for their medicine. 29

In this political environment moments of reform, and even expansion, of public delivery are regularly transformed into new accumulation opportunities. Despite the overwhelming popular support for universal care in the United States, the Medicare + Choice Act of 1997 and the Medicare Modernization Act of 2003 are good examples of how 'reform' is configured. The former Act tried aggressively to funnel public funds through HMOs, by contracting with them to cover Medicare for seniors. The latter Act supplies a very spotty prescription drug coverage for seniors (roughly 22 per cent of costs will be covered, according to the Congressional Budget Office), while creating incentives to process this coverage through for-profit channels, explicitly prohibiting the purchase of cheaper drugs from Canada, and disallowing any use of federal bargaining leverage to reduce drug prices. 30 Presidential and Congressional administrations of both Democratic and Republican stripes pay close attention to industrial advocates, harnessing public demand for the optimal — i.e. least offensive — financing and provision scenarios. The fanfare of the Obama Administration is very unlikely to change this, although it may occasion a rolling back of some of the previous administration's more egregious corporate hand-outs (particularly the Medicare Advantage program, in which private insurers received an extra 14 per cent on regular government reimbursement rates simply for taking on Medicare recipients). 31 Private insurers are positioning themselves to take on the remaining population who currently lack health coverage, but with a strictly controlled number of benefits. This will likely be the political trade-off for the Administration — extension of coverage to the full population, but only with 1) the preservation of market-led, segmented health financing, and 2) reduced expectations on the part of enrollees. With a firmly entrenched financing and provision configuration that privileges private over public transactions, market advocates have time on their side. To create meaningful solidarity systems requires an all-or-nothing approach, whereas accumulation by institutional adaptation involves only incremental change. 32

There is no doubt that, in a broader international context, all service industries have generally sought to carve out greater opportunities for accumulation. The Global Services Coalition, for instance, recently told the leaders of the G-20 countries that 'r[enewed and reinforced commitments by leaders to maintain open markets and to provide enhanced opportunities for growth through further liberalisation are needed urgently'. 33 In relation to health the desire of American and European service providers to expand operations is particularly clear, and given the comparable size of the health markets in OECD states the possibilities of increased private accumulation in health delivery are substantial. The Coalition of Services Industries (CSI), representing US service firms, regrets the fact that '... health care services in many foreign countries have largely been the responsibility of the public sector. This public ownership of health
care has made it difficult for U.S. private-sector health care providers to market in foreign
countries. As such, it aims at 'obtaining market access, national treatment commitments, and
the right to fully own healthcare facilities in foreign markets'. American style managed care has
long been the US's principal health-oriented export to many countries in South America. Such
precedent-setting incursions into middle-income markets may form the basis for enhanced access
within OECD systems in the future.

Certainly, the ongoing attempts to expand and foster bilateral and multilateral trade agreements
in the areas of intellectual property (IP) and services lays the basis for altering public/private
configurations in a number of countries. Elsewhere, I have referred to a 'TRIPs/GATS nexus within
the WTO process — but applicable to a host of other trade arrangements as well - that forms the
basis for expanding the accumulation potential of private US health providers in foreign markets.
While such agreements suggest the strong potential for incursions into the domain of health, the
behaviour of the United States Trade Representative (USTR) in recent rounds of the 'Special 301'
process is even more telling. With trade sanctions and the threat of withdrawal from the
Generalised System of Preferences to back them up, the 'Special 301' trade mechanism furnishes
successive US executives — both governmental and corporate — with powerful leverage above
and beyond the multilateral negotiating process. Corporations regularly consult with the USTR to
use 'Special 301' on issues of intellectual property (IP) infringement, as a way to protect current
and future accumulation strategies which they deem threatened by the public policies of non-US
territories. Utilising this leverage, PhRMA and the USTR have recently catalysed a dramatic shift
in trade policy, specifically with regard to healthcare regulation and delivery.

PhRMA, like the CSI, has long protested over the public delivery of health care across the
OECD world. In relation to Germany, the PhRMA decried the fact that 'physicians operate under
strict budgetary controls' and that these 'create a bias away from innovative therapies that may be
the most appropriate for patients. The end result is that U.S. companies are disproportionately
impacted because U.S. industry is the global leader in bringing new drugs to market'. Until
recently, this kind of protest appeared as background noise, but the biopharmaceutical industry
has now thrown its full support behind a reformulation of trade policy in this area. PhRMA's 'Special
301' submissions to the USTR now go well beyond intellectual property concerns, directly into
areas associated with public delivery. PhRMA's submission requests that both Canada and
Germany be listed as 'Priority Foreign Countries', the most severe of 'watch categories' under the
301 Report. These countries' ostensible IP offence has been the maintenance of 'price control' and
healthcare regulation, now understood as trade barriers for innovation-based industries. For
example, Germany's attempts to get Healthcare spending under control are said to 'distort the
marketplace, limit market access for US research-based pharmaceutical companies, and deny
patients the most effective medicines'. The USTR's Special 301 Report reproduces this industry
language, indicating a dramatic shift in government policy. The report, mandated to deal
specifically with IP issues, now focuses attention on

regulatory barriers that impede [industry's] ability to sustain the cycle of innovation and
may inhibit the availability of new, groundbreaking products. These types of regulatory
barriers include, for example, non-transparent administrative regimes; decision-making that
lacks a scientific basis; and cumbersome and lengthy drug listing and other administrative
processes.

The document goes so far as to list, in detail, the regulatory barriers which Canada and
Germany are said to maintain through their healthcare cost control policies. Such deliberate
attempts to extend the use of unilateral trade mechanisms are indicative of a trend set by providers
to expand the basis for enhanced private accumulation outside the already swollen US market.

The degree to which stronger incursions into health markets can be successful remains an
open question. The United States may represent a kind of paradigmatic private health market, but
since accumulation by institutional adaptation necessarily reflects national circumstances, this
means that replication of the US model is in no way guaranteed. It is hard to evaluate the extent
that public/private configurations have been altered, because much depends on whether you view
the question quantitatively or qualitatively. In the case of the former, Chris Holden argues that, to
date, there has been a slow but steady advance of private provision in health care, most
dramatically in countries in the global 'south'. Here, the influence of international organisations,
primarily the World Bank' and International Monetary Fund, is extensive in promoting privatised
care. Advances in OECD countries are, according to the data, more limited, but 'the political
climate suggests that a more fundamental trend may be underway'. This largely fits with
advocates' expectations that managed care 'opportunities' will be greatest in southern countries
where, after the United States, out-of-pocket spending and private health insurance are most
prevalent. In European-style systems, by contrast, such enthusiasts argue that managed care's
greatest prospects lie only in complementary forms of health coverage and provision. The
numbers suggest a convoluted mix of public and private provision in the OECD countries that is not
apparently swinging rapidly in favour of the latter. However, a qualitative look at the kinds of
restructuring that have taken place suggests at least the strong potential for more pronounced
change. After all, accumulation by institutional adaptation does not require wholesale
transformation — incremental 'tinkering' can, over time, maximise private actors' opportunities,
even within public or quasi-public venues.

Considered more closely, one finds varying attempts within OECD countries to redesign health
systems that parcel out greater autonomy to public healthcare 'trusts' or regional and local
authorities. Across Europe, delivery systems are being reconfigured to maximize performance, with
very little public admission that such reconfigurations may form precursors to enhanced
privatisation. Much is made in health literature of the 'purchaser-provider split', and it is, no doubt, a
significant warning sign that public provision is changing shape. The objective, putatively, is to
create 'efficiencies' by devolving authority, and autonomy, to regional or sub-national agencies that
are, in turn, responsible for leveraging better conditions from providers. The similarity to — and
often direct borrowing from — managed care arrangements in the US is unmistakable. In the case
of the UK's National Health System, this has been precisely the approach, both in terms of regional
health financing and hospital provision. Stewart Player and Colin Leys have outlined how such
autonomy, combined with a strategic national orientation to involve more private provision, can be
used to fragment a single-payer health system, so that private accumulation is both enhanced and guaranteed. Far from efficiency, the result is 'a change in focus: a switch from a national to a
local programme of procurement of an extended range of services from the private sector, but with the
overall scale of funding unchanged, if not expanded'. This trajectory is in no way limited to
'solidarity' systems (such as those of Sweden, the UK and Canada), as the case of Holland's social
insurance reform makes abundantly clear. Although reform of Dutch healthcare financing and
delivery has involved devolution of authority that still ostensibly protects solidarity, it is not a very
radical step from decentralisation or autonomisation to subsequent forms of privatisation. In the
Dutch case,

... the new health insurance legislation will have a profound impact upon health care, in
particular upon the concrete meaning of the concepts of solidarity and equal access, going
far beyond what many expect from it. The tensions between the public function and private
structure will work as a driving factor. The tension will be resolved by a redefinition of what
the public function of health insurance legislation should be.

It is important to note that divisions between healthcare purchasers, whether in public, private
or hybrid form, foster or ensure diminishing cost leverage and population-wide planning. This is the
optimisation effect of the industry's pragmatism, wherein private providers can accumulate capital
flow within the system, and those responsible for planning and purchasing retain less-than-optimal
influence over either pricing or which substantive procedures and/or products are authorised for
reimbursement.

The industrial core of health needs, then, to be properly seen in its entirety. The alteration of
health care systems cannot be seen as a coincidental restructuring stemming merely from either a
fiscal crisis of the state or an ideological rejection of welfare structures. Instead, the total purchase-provision-profit cycle must be understood as a tactical pressure-point in an industrial strategy for new and expanded avenues of accumulation. This is why, for instance, biopharmaceutical corporations invest their energies across the board, from searching out and purchasing patentable research, to ensuring the viability of products among clinical practitioners, to prying open or adapting elements of healthcare delivery for their advantage. In order for corporate and state strategies to obtain the future returns touted by industrial advocates, all elements of the industry will be expected to work in sync, minimising the effects of expenditure control and maximising the domain of health production in our lives.

**Regulatory Outcomes and Certainty**

In the context of large societal investments in health-related research, production and delivery, the regulatory conditions surrounding health have become the subject of considerable scrutiny. As states supply infrastructural capacities to foster expanding accumulation in health, they also come under pressure to ensure that the mandate to protect citizens translates into mechanisms that ‘...do not constitute unnecessary barriers to trade in services’, and are ‘...not more burdensome than necessary to ensure the quality of the service’. Here, virtually all players — corporate, state and institutional-academic — are invested in a similar outcome: regulatory regimes that facilitate the production-provision-profit cycle. This gets projected as a harmony between market and civic objectives, but it is more likely that regulatory conditions are being increasingly drawn into a process whereby government oversight is harnessed (but never fully captured) to achieve increased certainty within an uncertain capitalist market.

While there is no space here to cover the myriad regulatory structures that relate to health across states, the US example again presents a valuable reference point. The Food and Drug Administration (FDA) promotes itself as the world’s 'gold standard' for human health product review, and it is fair to say that many if not most other national agencies follow its lead. Embedded in the most market-oriented system of health production and delivery in the world, the FDA nonetheless represents a curious mix of governmental mandate and corporate loyalty. While biopharmaceutical firms, along with segments of Congress, like to characterise it as a slow-moving governmental behemoth, the FDA has in fact become a finely tuned instrument of industrial legitimisation and protection that these same actors would hardly relinquish. As such, exploring the contemporary state of the FDA reveals something about the two-sided nature of accumulation by institutional adaptation, and shows how building a market can go hand-in-hand with avoiding competition.

The FDA has garnered broad appeal as a regulatory institution of public trust, particularly in relation to human health. It carries the responsibility for regulatory review of all biomedical commodities in production or circulation within the United States and should operate with a priority for public health and safety. As with all regulatory agencies, it must tackle issues of potential conflict of interest: how closely can advocates of a particular social objective (enhanced biomedical production and its profitable realisation in the market) be linked to the regulation of that same objective? In view of the heavy civic burden it bears, it would accord with common sense to find a critical distance between FDA regulators and industrial and/or state advocates. At a foundational level, however, this proves largely untrue. The Congressional oversight bodies that give life to the FDA’s mandate are the same ones that have supported and bolstered the health industry in its three-decade long expansion •within and beyond the American market. One result of this is a contradictory plea from policymakers and regulators alike: maintain rigorous standards for regulation while facilitating robust industrial development. Even the staunchest Congressional criticism of lax pharmaceutical regulation always stops short of challenging the 'legitimate incentives and rewards for innovative drugs and biologies'.

In fact, the FDA forms one of the central arenas in which the 'fuzzy' boundary between state regulation and industrial advocacy is most evident. Increasingly, the very power source that afforded the FDA relative autonomy from the industry it regulates — its governmental funding
source is being eroded. In 1992, under enormous pressure from biopharmaceutical corporations (as well as patient advocacy groups) to step up approval times, Congress passed the Prescription Drug User Fees Act (PDUFA). Under this legislation - subject to review every five years - corporations pay a user fee for their drugs and biologies approval applications. The legislation ensures that the funds are used only for this purpose and that certain benchmarks (set out by Congress) are met. PDUFA continues to meet with overwhelming support in Congress, heralded as the source of patient well-being, regulatory streamlining and a boon to US competitive practice. Throughout periods in which the act has been reviewed, policymakers state incessantly how obvious it is that Congress must 'ensure quick, clean, reauthorisation', and that such actions will 'guarantee patients' continued access to innovative drugs, and meet our country's gold standards of safety and efficacy'. More than just a 'pet project' of Congressional members, however, the results of the PDUFA are touted by PDA officials as emblems of American competitive success. Indeed, the PDA's key criterion for evaluation of this programme is how quickly the agency is able to accelerate processing times. In testimony, PDA Deputy Commissioner, Lester Crawford, boasts of the link between PDUFA and industrial competition:

We now have 8 years of data on our efforts to achieve PDUFA goals. During this period the PDA faced a total of 73 performance goals. We met or exceeded 71 of those goals. If you add procedural goals to that total, the Agency met or exceeded 86 out of 92 PDUFA goals. The result has been a dramatic reduction in product approval times. Drugs are now reviewed in the U.S. as fast or faster than anywhere in the world, without compromising the very stringent standards that Americans have come to expect. With the enactment of PDUFA, U.S. companies have overtaken their European counterparts, and now have a commanding lead in world markets. A July 2001 report found that the European share of the world pharmaceutical market fell by 10 percent over the past decade, while the U.S. market share rose by more than 10 percent.

This unabashed support for accelerated approval times has met with serious criticism. While there are no existing systematic studies, strong anecdotal evidence suggests that the PDA has grown far too close to the industries that it ostensibly regulates. This has fostered an atmosphere in which safety precautions are downloaded onto physicians; extraordinary pressure is placed on drug reviewers (even the Director of the Center for Drug Evaluation and Review admitted publicly to a 'sweatshop' environment), resulting in a 'revolving door' turnover pattern; and there is a prevailing 'basic message to approve'.

The results of such a 'cooperative' relationship between state and industry can be said to go well beyond the acceleration of approval times. It reaches, instead, into a range of industry-friendly policies designed to maintain or improve upon conditions for accumulation — from slow administrative reaction to failing drugs, such as Vioxx, Redux and Prozac, to lax standards on direct-to-consumer advertising and post-marketing surveillance of drugs, ongoing agency-related loopholes on patent and exclusivity extensions. Recently, the PDA went so far as to block the re-importation of US-produced prescription drugs from Canada. Although they had been cleared by the PDA, their brief time in Canada was used as pretence to label them 'unsafe'. This transparent move was aimed at protecting US pharmaceutical firms from their own products, which are far less expensive (often due to price regulation) outside the US market. Accumulation by institutional adaptation operates here in a manner that goes beyond 'regulatory capture', a situation in which state agencies come to identify too closely with the groups they regulate. Instead, there is an interlocking dynamic of policymakers, regulatory officials, corporate players and extremely sophisticated industrial lobby groups. At most, this merits occasional concern among politicians: to quote Representative Sherrod Brown again, 'when the drug industry wants us to move quickly to ensure that the PDA doesn't hold their products up from getting to the market, we move with lightning speed to do their bidding.' Since the PDA is engaged in a public-private partnership to facilitate the competitive position of the US health industry, its objectives are to foster certainty and fend off destabilising threats. When it appears to industry advocates that these objectives are compromised, the reaction is swift and telling. For example, when the PDA considered invoking its
authority in limited cases to require manufacturers to switch drugs from prescription to over-the-counter status, opponents argued that 'to allow such a practice would create uncertainty and unnecessarily complicate the already highly risky business of drug development. New research and development would be chilled as a result' 62 This threat summarises the endgame in most regulatory debates related to health: any conditions that make accumulation less than optimal are said to be inherently obstructive to innovation and, therefore, detrimental to quality of care for citizens. In the end, regulatory institutions are a terrain of struggle for industrial advocates, who use threats of diminishing quality to enforce the further integration of the state and the health industry and ensure that the pursuit of generous profits in the health sector remains a worthwhile endeavour.

Conclusion

The corporate presence in biomedical research, treatment options and healthcare delivery assumes new forms each day, particularly in the wake of greatly augmented trade and market possibilities, actualised globally in the WTO and regional trade agreements. Human agency within such a commodified field is, of course, complicated — we are, after all, eager patients of our own volition. A profoundly difficult question emerges out of the health industry's accumulation strategy: how much health is enough? Efforts to massage increased corporate access into even tightly regulated systems means decreasing influence of structures that might otherwise have limited surges in medicalisation. In middle-income and 'northern' economies, where corporate objectives are especially intensive, populations are all too well disposed to 'acquiring health'. As the late biochemist Erwin Chargaff bluntly put it, 'we've turned into such outrageous whiners. Just as humans are not born to be rich, they're not born to be healthy. Health is nice, but it's not an argument. People live longer now, but how do they live longer? And why?' 63 For all their faults, publicly-oriented life science and health delivery systems make choices about human need that derive in some way from social consensus rather than accumulation potential, and it remains a critical social brake on our increasing desire to both medicalise and 'performance enhance'. 64

The difficulty is that the politically pragmatic strategies of the health sector have worked ingeniously to blur the lines between private and public objectives. There is no health system, no existent combination of purchase and provision, which avoids the scenario wherein private actors make the most of public objectives. As this essay has tried to show, those who provide for health - whether through product or service — ensure that profit streams are maximised. In more solidaristic societies, we find attempts by the industry to undermine, to the extent that it is politically feasible, the mechanisms which seriously restrain growth in health spending; not necessarily aiming for system transformation, but seeking to harness existing institutions for maximised returns. In less than solidaristic systems, especially the United States, we find a vigilant effort to ensure that 'dangerous' policy precedents (such as those that would lead to general price control) are placed in check, watered down, or morphed into something more palatable. Despite all the claims about efficiencies, whether public or private, those who purchase health care are experiencing less cost leverage as a result of autonomisation, regionalisation or localisation. Meanwhile, regulatory bodies still play prominent roles, but with their objectives subtly altered, through changes in policy-making environments and/or their sources of funding. In this milieu, the push to expand health spending — to realise profit on the full array of corporate, state and institutional health-related investments — can only intensify. The fact that OECD countries, in particular, have bet on health as the growth sector of the future will mean no shortage of protagonists at all levels of this process. This is why projects of universal health care remain highly significant: as a check on medicalisation (now largely a function of commodification) and as a barrier to the health industry's strategies for maximising its accumulation potential. To the degree that universal planning — whether through highly regulated but localised systems or through single-payer systems - can be defended, the expansive imperative of the health industry can also be held at bay, for the good of citizens and patients alike.
Endnotes


6 Albo, 'Contesting the "new capitalism"', p. 79.


14 US Senate, 'Paying off generics to prevent competition with brand name drugs', Testimony of Billy Tauzin, Committee on the Judiciary, 17 January 2007.


17 US House, 'NIH: moving research from the bench to bedside', Committee on Energy and Health, Subcommittee on Health, 10 June 2003.


21 AdvaMed speaks on behalf of more than 1300 of the world's leading medical technology corporations and manufacturers of medical devices, diagnostic products and medical information systems.


24 US House, Testimony submitted for the record by the Advanced Medical Technology Association, p. 6.


11. CSI, 'Response', p. 66.


13. Rodney Loeppky, 'International restructuring, health and the advanced industrial state'.

14. 'Special 301' is the name given to an annual process whereby the US government identifies countries that in its estimation deny adequate and effective protection of intellectual property rights or fair market access to American industries that rely on such protection. See Lisa Peets, Mark Young and Marney Cheek, 'Special 301', available from http://www.cov.com.


18. PhRMA, 'Special 301 Submission', p. 16.


21. Ibid., p. 685.


28. World Trade Organization, General Agreement on Trade in Services, article VI.4andVI.4(b).

29. For one such example, see Joel Lexchin, 'Drug safety and Health Canada: going, going.. gone?', Canadian Centre for Policy Alternatives, April 2009.


58 See testimony of Janet Woodcock (Director, Center for Drug Evaluation and Research) before US House, 'Recent developments which may impact consumer access to, and demand for pharmaceuticals', Committee on Energy and Commerce, Subcommittee on Health, 13 June 2001; see also John Swasy Aikin and Amie Braman, Patient and Physician Attitudes and Behaviours Associated With DTC Promotion of Prescription Drugs, Report for US Department of Health and Human Services, PDA and Center for Drug Evaluation and Research, November 2004.
60 This extends to the medical instrumentation industry, with a Medical Device User Fee Act (MDUFA), also highly coveted by relevant industrial actors. See: Ernst & Young, Pulse of the Industry, p. 23.
63 Jordan Mejias, 'Research always runs the risk of getting out of control', Interview with Erwin Chargaff, Frankfurter Allgemeine Zeitung, 4 June 2000.