

The Globalization of the Pharmaceutical Industry

Written for Professor Karen Pinkus's COLT 303

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As one of the world's most profitable enterprises, the \$500 billion, multinational pharmaceutical industry can earn \$10 billion a year on sales for a single product. With such an enormous cash flow and a pervasive influence on international policy and public perception, Big Pharma is in a better position than supranational assemblages like the World Health Organization to combat health crises around the world, including epidemics of easily treatable diseases like malaria and diarrhea which still kill millions of people a year. But these progressive goals are not the industry's priority. By using neoliberal globalization's opportunities to cut costs and maximize profits, Big Pharma is now directly contributing to international public health crises. The top drugmakers are exacerbating an inequality of drug access by heavily policing an international "patent regime" that squashes the efforts of the developing world to medicate its own people. Outsourced clinical trials exploit the populations of the developing world by subjecting them to experimental drug treatments that nobody in the developed world wants to risk, and the results are used in expensive multinational drug marketing campaigns that skew cultural notions of well-being for the maximization of corporate revenues. These various symptoms must be collectively assessed to understand not only how globalization has ensured that "the market alone will not provide adequate drugs to poor people, or ensure the development of drugs for diseases primarily affecting the poor" (Bull and McNeill 65), but also to become aware of how Big Pharma is driving and being driven by globalization towards a corporate monopoly of just a few multinational giants whose profiteering agenda is fundamentally changing whom and what are considered worth healing.

The processes necessary for the pharmaceutical industry's growth can be divided into three broad categories: those relating to production, research and development, and marketing. All three segments of the industry interact with globalization in such a way as to ensure that the

spread and influence of the multinational pharmaceutical industry continues to escalate, but not in a manner that fosters market diversity – rather, the top multinational conglomerates of the developed world simply keep getting bigger and more profitable, while the ability of start-up drug industries and sick peoples of the developing world to supply and access badly-needed medicines is being undermined and their populations exploited by Big Pharma’s cost-cutting maneuvers.

Drug Manufacturing – Global Relocations and the International Patent Regime

It is difficult to thoroughly investigate the production lines that Big Pharma extracts active ingredients and synthesizes chemicals with, because of the secrecy surrounding these proprietary methods of drug production. However, geographical patterns of production can at least be traced, and have been seen to follow the general trends of neoliberal globalization: factories relocate to places where overheads are lowest. This was the case when Clinton made a literal economic island out of Puerto Rico by granting “special provisions for the extension of tax benefits to businesses looking at Puerto Rico to establish or expand operations,” which for a time made Puerto Rico one of the top five drug-making centers in the world (PIA-PR.com, Associated Press 2007). Those factories also left Puerto Rico for sites in Asia when those tax incentives were lost in 2007, laying off 3,000 high-paying jobs and ensuring that things were “going to be pretty bad for a lot of people,” as a local construction worker commented to news agencies (Associated Press 2007, Gale 2007). In this regard the pharmaceutical sector is as guilty as any other globalized industry for “evaporating” labor (Klein 201).

Given the necessarily skilled labor of pharmaceutical industrial engineering and the paranoid secrecy with which the industry guards its production patents, it seems that most of

these relocated factories would emerge in other places as fully proprietary production sites instead of being truly outsourced to host country contractors (Law 14, 74). If true, it might be inferred that the exploitation of outsourced labor that Naomi Klein has documented the globalized textile industry as utilizing does not occur (Klein 202). However, the manufacturing process itself can be split into unskilled tasks like the “limited mixing of several purchased inputs,” and at least one pharmaceutical representative has commented on how much of the industry’s recent focus has been on “outsourcing to lower-cost but highly effective companies in Asia” (Abdelgafar 112, Gale 2007). An industry guide to outsourcing provides a justifying rationale of how, “with high fixed costs and a correspondingly high level of government interaction, it would be difficult to realize manufacturing economies without jeopardizing standards of quality or future capacity” (Piachaud 117). But since “production licenses are often obtained by individuals who do not themselves have any manufacturing capacity but will sell or lease the license to any available and willing manufacturer,” it is wholly possible that those “standards of quality” *are* jeopardized since the final manufacturer could avoid regulated inspection simply by being so difficult to pinpoint (Abdelgafar 112).

How many of these truly globalized production outlets there are and their conditions of labor are not public knowledge – PIA-PR, the industry’s publicity outlet for operations in Puerto Rico, has many restricted areas on their website and in a publication geared towards the prevention of industrial pollution the US Environmental Protection Agency even cited the “competitive” pharmaceutical industry’s unwillingness to “divulge details pertaining to their processes” (PIA-PR.com, Environmental Protection Agency 1991). However, hints as to what these globalized processes could be shortcutting are beginning to surface with independent accounts of mass amounts of pollution from the effluent runoff of outsourced Indian factories

(Cox 2005). Abdelgafar shows how the global pharmaceutical players even use outsourcing to threaten and persuade developing nations to bend to their agenda: Egypt's government is under constant threat of losing its foreign-contracted drug production centers to Gulf countries if they do not eliminate their drug price controls (136). If these methods and attitudes are standard for the outsourcing of pharmaceutical production, then it is clear that the public health of developed nations is coming at the expense of the public health of the developing world, and that this paradigm is acceptable and taken for granted by the industry.

The impetus for the move of Swiss-based Roche's production centers for the antiviral drug Tamiflu to China's Shanghai Pharmaceutical Co. also illustrates the influence of globalized drugmakers on local, host country populations. Roche's Tamiflu has for years now been considered the "only defense the world currently has against the threatened [avian] flu pandemic," and governments, corporations, and individuals were at one point clamoring for stockpiles of the drug (Laurance 2005, CIDRAP News 2006). However, the production of Tamiflu was hampered by the low supply of star anise, which is a Chinese tea herb that had before been used as a traditional treatment for infant colic and as a cold medicine (Fong 2005). It was found that a chemical compound vital for Tamiflu synthesis could also be extracted from star anise in relatively high quantities, and during 2006's flu scare about 90% of the world's pharmaceutical star anise was coming from Guangzi Province in China (Garner-Wizard 2006).

Oguamanam points to the "stress" that "international economic and political forces" place upon local communities to "exploit their natural resources," and such was the case for star anise: national governments pressured Roche to increase supply to meet stockpiling need, and the demand was felt by Guangzi farmers who immediately planted more star anise trees to compensate (Oguamanam 55, Garner-Wizard 2006). Workers were paid only "about \$3 a day to

scramble up the misty hills to pluck the fragrant pods” – a sum arguably more than the usual Chinese peasant subsists on, but still very low given the 34% increase in billion-dollar profits that Roche saw in 2007 (BBC, 2007). However, star anise trees take 6-10 years to bear fruit, and the industry has already moved on to forms of chemical extraction that would not require star anise (Garner-Wizard 2006). This will eradicate the 4-cents-a-pound market that Chinese peasants intended to satisfy with their investment into more star anise trees, leaving them penniless (Fong 2005). Roche will not assist them.

In fact, prevailing wisdom among developed nations and the mega-pharmaceuticals they harbor states that the developing world ought to be able to manage handsome profits from their bioresources like star anise. This assumption is based on the Western model of intellectual property rights, which the global North prescribes to the global South “as an instrument of technology transfer and as capable of enhancing the latter’s economic development” (Oguamanam 7). This technology transfer fails to happen, since Big Pharma outsources only very limited segments of the production process to overseas production centers. Roche has even “held out against” granting full production licenses to overseas manufacturers with paternalistic arguments that “the production process is complex and involves the use of potentially explosive chemicals” (Wright 2005). The global South also certainly does not exercise intellectual patents to the “aggressive” level that the global pharmaceutical giants protect their bioprospecting endeavors with (Oguamanam 7). It has been argued that patent laws as “industrial and free-market models” are even antithetical to “non-Western cultural milieus,” and the expectation for developing countries rich only in biodiversity to exercise strong patent laws represents a form of cultural imperialism (Oguamanam 61).

At the end of 1994's Uruguay Round of the General Agreement on Tariffs and Trade, supranational bodies took this cultural imperialism and drafted it into a controversial document that emphasized rigid protection of intellectual property rights. This was the TRIPS Agreement (Trade-Related Aspects of Intellectual Property Rights), which now holds all WTO members responsible for increasing the scope, duration, and geographical coverage of industrial patents (Walker x). "There is no mention of the informal, traditional, or ecological knowledge of local people" in the TRIPS Agreement, further marginalizing the sociocultural contexts that indigenous cultures' uses of genetic resources "thrives in" (8). It has also has been pointed out that TRIPS "sits uneasily with the other agreements of the WTO" because it flies in the face of even neoliberal ideals by promoting "intervention in the market to protect private property rights" (Walker x). Therefore, in addition to the cultural suppression of local lore, TRIPS also suppresses the growth of developing nations' own domestic pharmaceutical industries, which depend in large part on the reverse-engineering of leading drugs to gain knowledge and experience for the development of their own production process (Abdelgafar 66, Lakoff 113).

The benefits of such derived knowledge are not limited to only those who figure it out. When Cipla and Ranbaxy, India's most advanced domestic pharmaceuticals, discovered how to reproduce the antiretroviral treatments for AIDS that Big Pharma had been producing and selling for \$15,000 a year, they improved upon them by combining other copied drugs into a cocktail of their own. Generic production of this Indian-made AIDS treatment reduced prices to only about a hundred dollars a year. Nonprofits and activist groups soon began importing the cheap generic AIDS medications to AIDS hotspots around the world, much to the disgruntlement of the multinational drug companies. Thirty-nine of them ended up suing South Africa's government in 1998 for just importing the Indian drugs, and by blackmailing India's effort to join the World

Trade Organization with TRIPS enforcement, “crippled” India’s generic drug production and eliminated the world’s hundred-dollar-a-year AIDS treatment (Shah 15, Law 74-75).

There does exist an oft-debated clause of TRIPS that exempts nations facing public health crises like AIDS from patent observation, allowing them to manufacture generic versions of vital drugs. But the United States has consistently opposed this “compulsory licensing” with international lawsuits and limits the drugs they will grudgingly allow to be copied – often with only a single AIDS treatment among them (Outterson 171-172). Barred from gaining the capability to produce their own medicines and left only with the option of purchasing expensive foreign drugs from large multinational brand names, developing countries are put in a difficult position. Although the big player pharmaceuticals utilize a pricing differential that adjusts drug costs according to individual nations’ GDPs (which also accounts for the price difference between Canadian drugs and American ones), these reductions are still not enough for most situations, especially given health crises such as AIDS, malaria, and tuberculosis that plague developing countries (Law 75, Graham 2002).

These top-down mandates from global assemblages like TRIPS support the static dominance of the few giant pharmaceutical corporations, but in an odd way they also stimulate the industry to escalate their global presence. The move of Tamiflu production to Shanghai would seem to be a prime example of pharmaceutical outsourcing, but for one important distinction: it was spurred by Beijing, rather than Roche. Most threatened by avian flu and yet forbidden by TRIPS to produce drugs for their own stockpile, the Chinese announced that they would violate Roche’s patent on Tamiflu and begin producing generic versions of the drug on their own unless Roche agreed to contract legally with their domestic pharmaceutical production

centers (Wright 2005). Roche gave in and Shanghai Pharmaceutical Co. began to prepare for legal production of Tamiflu.

Brazil found itself in a similar situation after having neoliberal structural reforms “unilaterally” introduced to it, and the former head of Brazil’s main domestic pharmaceutical Far Manguinhos recently confided to interviewers that her public laboratories had “already reversed-engineered two [anti-retroviral/HIV] drugs that were under patent production and were ‘ready to go into production if the government deems it necessary’” (Biehl 219, 226). In response, in 2001 the US threatened to bring down sanctions on Brazil should their Big Pharma patents be broken, and an uneasy agreement was reached where Brazil was allowed to break them so long as it did not export the resulting products (Biehl 229). These constitute instances of states learning how to participate in the global pharmaceutical “nexus”: they can “claim spaces of independence for themselves” by simply ignoring international copyright, and can also “undercut industry attempts to establish market strength by imposing strict regulations and procedures for product approval and advertisement” (Petryna and Kleinman 19). But as will be seen in the next section, the pharmaceutical industry not only hijacks these state attempts at regulation, but effectively escapes them altogether by shifting more than just production abroad – the critically important research & development process can also be outsourced, with disturbing ethical and cultural implications.

Global Drug R&D: Clinical Trials on the Poor

The commonly cited justification for outsourcing pharmaceutical research is the same as it is for production: other costs are rising, making it “increasingly difficult to allocate resources to such activities as R&D.” That the “rising costs of production” are often already offset by

outsourcing and that “such activities as R&D” ought to comprise the innovative backbone of any pharmaceutical enterprise are usually unmentioned by industry spokespeople (Abdelgafar 136). What *are* constantly mentioned are statistics on the mammoth expenses associated with producing drugs: the Pharmaceutical Research and Manufacturers of America (PhRMA), the most influential of the industry’s lobbying representatives, set up a study in 2001 that claimed to reveal the average cost of developing a pharmaceutical drug in the US to be \$802 million. But Sampath points out that this figure may have been inflated by as much as half, because “such estimates include not only the costs of R&D into potential leads...but also contain the costs of borrowing money to finance the R&D process and the marketing costs of the product (which can add up to approximately 40 per cent of all total costs)” (Sampath 16).

Despite such industrial figure-fudging, it is true that establishing a clinical research trial to prove the safety of new drugs has been considerably difficult ever since “unregulated medicines...killed thousands of Americans” in the early 20th century and prompted government intervention (Shah 37). Now, drugmakers are required to test their products in increasingly wide human trials before releasing them to the market, being obligated to run their drugs through Phase I toxicology tests, Phase II efficiency investigations, and Phase III overall evaluations (Piachaud 90-91). While the Phase III studies are called upon to involve only about one to three thousand human subjects, in reality, Big Pharma companies were typically forced to find one hundred thousand people for any one Phase III trial because “only a fraction show up for their appointments and of these only a fraction could be medically eligible” (Shah 3, Piachaud 91). The citizens of Big Pharma’s home countries opt out of clinical trials because they have options available to them other than untested, experimental medications: Pfizer’s eye-disease drug Macugen fared terribly in its American Phase III trial because nobody wanted to inject it directly

into their eyes (Shah 4-5). Accordingly, Americans in particular are the largest consumers of drugs but “less than one in twenty are willing to take part” in clinical trials (Shah 4). But *somebody* has to participate in these “valley of death” trials that “will take forever and will cost the earth,” so pharmaceutical executives have recently begun to look beyond Big Pharma borders for human guinea pigs (Shah 39, Piachaud 127).

Facilitating this global shift are Clinical Research Organizations (CROs), third-party outfits that take contracts from pharmaceutical corporations to run clinical trials and deliver results (Piachaud 127, Shah 6-7). The utilization of CROs for research and development is very analogous to the usage of third-party chemical manufacturers for drug production, with the same global implications. For a time the CROs kept their operations within national boundaries, but after a few drug applications based solely on overseas clinical trials passed through the FDA without incident, CROs and drug companies “streamed across the border” (Shah 7). As of 2003, America’s Pfizer and the Anglo-Swedish AstraZeneca have placed “global clinical trial hubs” in India, Britain’s GlaxoSmithKline has moved at least 30% of its clinical research to India and Poland, and just a single CRO has peppered trials all over South Africa, India, Southeast Asia, Latin America, and Eastern Europe (Shah 7, 9). This has made the largest pharmaceutical corporations truly “multinational enterprises,” and has also saved at least one big drugmaker up to \$200 million in R&D expenses (Abdelgafar 136, Shah 9). By 2004 there were more than sixteen hundred overseas trials running in Russia, India, South Africa, and other Asian and African countries (Shah 7). But as Shah points out, it is “the broken, impoverished countries of Eastern Europe and Latin America” that are especially favored by drug corporations and their CRO proxies for clinical research (Shah 7, Petryna 41).

Why this is reveals again how global neoliberalism begets globalized industry. David Harvey has extensively shown how the “structural reform” recommended upon developing nations frequently leads to national ruin, and in Eastern Europe this was precisely the case: “rapidly opening markets combined with economic shock therapy” prescribed by the IMF and the World Bank and the “strings-attached” loans that came with it diverted funds out of social service and health programs which were suddenly considered expendable (Harvey 92-119, Petryna and Kleinman 4-5, Shah 12-17). This pattern repeated itself throughout most of the developing nations that accepted neoliberal economic recommendations, from Zambia (whose “nascent welfare state was methodically dismantled”) to AIDS-ridden South Africa (Shah 25). The gaps in healthcare that these structural reforms created for the Third World allowed Big Pharma to fill the void with offers of badly-needed medication (Lakoff 113, Shah 16). Having no other domestic sources of treatment left, the sick populations of these ruined countries have only the Phase III clinical trials to turn to, which allows the Big Pharma R&D outfits to fulfill their obligatory trial quotas quite handily .

The attitudes of those who run the trials can be remarkably cavalier about this exploitation. “The real world is exceedingly painful,” noted one industry PhD – as if the “ill health of the developing world” were “as static and irreversible as the setting sun,” making it just as well that Big Pharma is taking advantage of it (Shah 10). Another story described a group of CRO researchers at a conference talking about how Western patients balked at “painful, invasive procedures” such as intravenous catheter insertion, while those in Russian clinical trials “were happy to do this as other alternatives were not available.” A colleague reportedly “chortled,” saying “I would not say that they were happy to do it, but they did it!” Giggling ensued (Shah 8-

9). The questionable sensitivity of these contracted clinical researchers may be anecdotal, but the questionable ethicality that they run their trials with can be criminal.

Most of the ethical controversies surround the exclusive usage of the placebo control in outsourced clinical trials' experimental designs. The most scientifically rigorous way to confirm that a drug actually works is to compare a group of subjects taking it to a group that is taking nothing at all, or taking an ineffective sugar pill (the placebo). The ethics of giving no treatment to the placebo group have been repeatedly attacked, especially if it is already known that the treatment is effective to some degree. As a study progresses, evidence for a treatment's efficacy will gradually reveal itself, and when this happens researchers as caregivers are ethically obligated to administer the treatment that works best. However, doing so would end the trial – and trials must be carried to completion to make the drug eligible for the market (Shah 19, Petryna 42-43).

With profits at stake, Big Pharma's overseas R&D proxies make decisions of dubious ethicality, and the results can be illustrated with anecdotes: "how could researchers justify looking HIV-positive pregnant women [in South Africa] in the eye and allow them to deliver their babies?" (Shah 90). In another case in Zambia, a new drug for diarrhea was being tested on HIV-infected toddlers in different groups. The first group received the drug and survived; the second group began their placebo treatment afterwards resulting in nine children dying. By the time the second group started their trial the positive data on the diarrhea treatment had already been known and other drugs had been available that could have saved the lives of those in the placebo group, but the data's integrity took priority (Shah 28-35). Because of the moral outrage that these scenarios cause, placebo trials have been all but discontinued in developed nations. However, Robert Temple, one of the chief regulators of the FDA, still continues to

wholeheartedly endorse the use of the placebo as the preferred method of research (Shah 28-29, 19). That he does so indicates that “the harm considered tolerable for experimental subjects varies, depending in part on where in the world the subjects live” (Shah 19).

The extent of this “tolerable harm” has been demonstrated; researchers are willing to let Third World babies die just to get a drug out on the market, and very real possibility of failed Phase III trials includes drugs that don’t work or are even more harmful than the placebo (Shah 19). Clearly, the global trends of pharmaceutical research and development are incredibly exploitive of less-privileged populations, and the benefits are rarely ever conferred to them either. Interestingly, however, these benefits may not be amounting to much for the developed world’s markets either. For all the dangers that the global poor risk in their compelled testing, “trends in the industry suggest that the margin of benefit for new drugs is rapidly shrinking” (Shah 37). Unless the industry soon develops breakthrough innovations on a level that has not been seen since the 1940s, the drug trial tribulations of the developing worlds’ ailing people may even come to be for nothing (Law 10). How the large multinational pharmaceuticals have kept the whole world from noticing the lack of innovation in their drugs is all due to an aggressive marketing effort that rebrands drugs as lifestyle accoutrements and even alters conceptions of health and disease.

Pharmaceutical Marketing: Branding Health and Determining Cures

The advertising game is one that the pharmaceuticals pioneered: as far back as the late 19th century when Merck sold cocaine and Bayer sold heroin, active ingredients in drugs were even then only known by “catchy slogans and advertising jingles” (Shah 37, Petryna and Kleinman 1). Acting on the logic of profits, Big Pharma’s marketing emphasis has today

become the dominant concern over production and R&D. Production is de-emphasized to the point where the factory has become “discarded,” which has been demonstrated by the difficulty in piecing together accounts of drug manufacture (Klein 201). Research and development now even “*is* the marketing”: not only do CROs splice trial results into prestigious journals and insert professional tabulations into FDA applications for their clients, but clinical trials are even designed “with marketing purposes in mind” to garner professional support (Law 45, Shah 7). Big Pharma openly acknowledges this, citing once more “intense competition and longer development times” to justify “a high promotional spend” as the only way they can recoup their investments and risks (Piachaud 118). A decade ago this high spend - \$1.3 billion - was between two and three times as much as was invested into R&D, and it can only have gone up since then (Shah 53).

The images and persuasion of pharmaceutical marketing easily transcends borders to attack a global market, despite having to do it in different incarnations depending on local conditions. Shanghai pharmaceutical employees hand out drug samples on city streets, African street vendors are supplied drugs to sell, and Indian pharmacists get color televisions from Big Pharma corporations for placing large drug orders (Petryna and Kleinman 16). Only the United States and New Zealand currently allow “direct-to-consumer” advertising of prescription drugs, which has also increased the prices of drugs in those places to make up for the astronomical advertising investment (Weber 158). Despite direct-to-consumer marketing being prohibited beyond these two countries, “the industry is fighting relentlessly for similar deregulation” around the rest of the world (Moynihan and Cassels, xvi). “Messages about drugs have become part of who we are and how we live in the global market, with its enormous hold on the transnational and domestic cultural space created by television and other advertising media,” say Petryna and

Kleinman, and there are numerous examples to prove them right of instances where particular drugs have altered the consciousness of what health and disease even are (16).

Viagra's exploitation of male mid-life insecurities for its treatment of "erectile dysfunction" is a favorite of Vince Parry, a Madison Avenue branding specialist who has assisted multinational pharmaceuticals with their marketing campaigns (Moynihan and Cassels, xii). Parry describes how drugs like these make it "not just about branding the drug," but also about creating whole patient populations by "branding the condition" (Shah 51). By manipulating the developed world's fears of death and decay and recasting First World conceptions of health as a "commodity and distinct personal achievement" with clever images and media advertisements, Big Pharma has tapped into a huge cash cow (Petryna and Kleinman 1-3). However, they have in the process redefined the "ups and downs of daily life," turning them into mental disorders, abnormal conditions, and broad dysfunctions (Moynihan and Cassels x-xiv). These depictions of "individualized health" make images of true health crises like AIDS appear "inchoate or hopelessly untreatable," which further marginalizes the developing nations that were exploited to even produce these treatments as populations that can be "valued and treated differently" (Petryna and Kleinman 3). The ridiculousness of the First World's focus on "lifestyle meds" is illustrated by allergy drugs: after more than \$100 million was spent by various big drug companies in an allergy med advertising war in 1997, disgusted HMO executives commented that "except for antibiotics we are spending more money on runny noses than anything else" (Shah 49-50). And yet those various drugs – Zyrtec, Claritin, and Allegra – were found to act almost identically (Shah 50).

Whole marketing campaigns have been built of air like this, and whether the uniqueness of the industry's biggest prize – its cholesterol-lowering statin drugs, of which Pfizer's Lipitor

leads global drug sales with yearly incomes of \$10 billion – has been similarly fabricated is being disputed right now. After a single study was released in 1985 that correlated low cholesterol levels with long life, Merck led the way with an “advertising and public relations blitz to paint cholesterol as Americans’ top health adversary,” then hyped up its first statin Mevacor the next year with rave clinician reviews.

It did not seem to matter that the costs of taking statins like Mevacor could bankrupt small countries and that simply dieting and exercising would confer much broader and safer health benefits (Shah 45, Moynihan and Cassels 1). Later studies would suggest the complete opposite: that people with higher cholesterol lived longer, half of all heart attacks occur in people with normal cholesterol levels, and that overuse of statins even disintegrates muscle tissue (Shah 54-55). Those who dared to publicize these studies would be personally slandered and have their professional careers criticized and undermined by industry marketing specialists (Shah 58-60). Such attempts to rectify public perception were at this point moot, anyway - the consumption of “lifestyle drugs” (that is, drugs which do not save lives from imminent death and sickness) had gone truly global, with Australians taking “ten times more antidepressants in 2000 than they did in 1990,” the number of Canadians on statins tripling in a decade, and prescriptions in the US for both these drug categories doubling in less than that time (Moynihan and Cassels xi).

Since the marketing of such drugs has reaped such rich rewards, they continue to be produced while truly life-saving cures go uninvestigated. The difficulties of drug production that Big Pharma consistently whines about just encourages the imitation of already-proven drugs by competing Big Pharma corporations to obtain some market share: after Merck released Mevacor, “copycat statins” continued to be released by the other top pharmaceutical players, with Bristol-Myers Squibb releasing Pravachol, Pfizer releasing Lipitor, Bayer joining with Baycol and

AstraZeneca chipping in Crestor (Sampath 17, Shah 53). Partly due to this sort of corner-cutting and also that there doesn't exist any FDA regulation requiring drugmakers to "invent high-priority drugs," only three hundred drugs of the thousands available in the US are classified by the WHO as being "essential for public health" (Shah 44, 53).

That lack of FDA intervention to force the industry to produce crucial, life-saving medications is critical, and even more so considering that neoliberal reforms in most countries relaxed approval regulations to depend only on whether a "leading country" had already approved the drug (Lakoff 113). Problems with the FDA (as one of those leading regulating agencies) are plentiful – it has become overworked by the high volume of non-critical drug applications with as much as three-quarters of its applications being for me-too drugs like the copycat statins (Shah 53), a new system of applicant payments has meant that half the agency's work is now being funded by the same pharmaceutical corporations it is trying to regulate (Moynihan and Cassels 19, Petryna and Kleinman 11), and it is even estimated that 90% of those "writing guidelines for their peers" on it have conflicts of interest due to financial ties to Big Pharma (Moynihan and Cassels 4). Regulators have proved poor defenders from the practiced marketing of the multinational pharmaceutical industry, which increasingly with globalization determines on its own what drugs will be produced, where they will be developed and manufactured, and how expensive they will be.

The Globalization of the Pharmaceutical Industry: "The Ever Growing Pharma Monolith"

Globalization has been seen to be aiding the pharmaceutical industry in reducing production and R&D costs, despite continued assertions that those costs are extravagant and justify massive marketing expenditures that go on to net huge revenues. These effects combine

to spell out big profits for the industry, and in 2003 only ten drugs earned almost \$50 billion (Law 8). Normal profit margins are 40%, which does not even include the high wages that workers in such a knowledge economy receive (Law 34). However, the escalation of profits for such a few number of products always necessitates greater and greater amounts of capital to be sustainable (Law 31), and periodically the top players of pharma devour each other in gigantic megamergers. When Glaxo took over Wellcome it cost \$14 billion. When GlaxoWellcome transformed into GlaxoSmithKline it took \$76 billion (Law 33). The Anglo-Swedish AstraZeneca represented one of the first truly single-but-multinational firms and Pfizer practiced its own brand of expansion via aggressive acquisitions (Law 32).

It seems that, at a certain point, all of these mergers will simply aggregate Big Pharma into a single, gigantic corporate monopoly. The sheer amount of money that this will place in just a few hands ensures that disingenuous global marketing campaigns will continue to be funded. The resources available to singular megacorporations (number-one drugmaker Pfizer is estimated to be worth \$200 billion) make it is likely as well that the developing world will continue to be exploited for cheap labor and drug testing because of the transnational expediencies that neoliberal globalization affords the wealthy (Moynihan and Cassels 3). While government has the obligation to protect the people, only industry so far has demonstrated the capacity to do that – but they have not demonstrated any inclination to do so. Much hope is being placed in public-private partnerships that might see global pharmaceutical giants and national governments work together in solving public health crises (Bull and McNeill 65-70), but these policy plans are dependent on the convergence of state and industrial interests.

Globalization has given the top pharmaceutical industries the power to dominate not only health policy and pharmaceutical access for the whole world, but by extension also the ability to

change perceptions of who is worth giving healthcare to and for what. At stake is the public health and cultural dignity of both the developed and developing nations, as well as hopes for future drug innovations of any significance.

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