PROOF

LIVELY CAPITAL

BIOTECHNOLOGIES, ETHICS, AND GOVERNANCE IN GLOBAL MARKETS

Edited by Kaushik Sunder Rajan

DUKE UNIVERSITY PRESS DURHAM AND LONDON 2012

Tseng Proof • 2011.10.17 07:41 8968 Rajan • Lively Capital • Sheet 3 of 506

PROOF

1

JOSEPH DUMIT

PRESCRIPTION MAXIMIZATION AND THE ACCUMULATION OF SURPLUS HEALTH IN THE PHARMACEUTICAL INDUSTRY

The_BioMarx_Experiment

The late Roberto Goizueta transformed Coca-Cola in the early 1980s. He had an insight—a simple but stunningly powerful one that he shared with his senior executives. What, he asked almost casually, was the average per-capita daily consumption of fluids by the world's 4.4 billion people? The answer was: 64 ounces. And what, he asked, is the daily per-capita consumption of Coca-Cola? Answer: less than 2 ounces (Charan and Tichy 1998). "We remain resolutely focused on going after the other 62," Mr Goizueta said (Coca-Cola Company 1996, 6). However absurd Goizueta's redefinition of the Coca-Cola Company's market might seem, it has been taken as a key transformative insight throughout the business world, demonstrating that "every business is a growth business" (Charan and Tichy 1998, 435). And that "virtually infinite growth" is a matter of finding the right formulation for the virtual and then actualizing it. One pharmaceutical parallel to global human liquid consumption is illness risk and the capacity to take drugs to ward it off. The more I read about markets and talk with pharmaceutical marketers, the more it seems as if this unbelievable growth in therapeutic consumption to ward off the risk of illness is happening. In this chapter, I elaborate the logics within the pharmaceutical industry that naturalize such growth.

Over the last twenty years, many scholars in medical anthropology and allied fields, including myself, have studied pharmaceutical resistance—pill

PROOF

diversion, strategic noncompliance, complementary and alternative medicine, and organized antimedicalization movements—as positive, creative, agentive challenges to the U.S. health system. While such resistance is widespread, the scale of our analyses has been enveloped (though not eclipsed) by the more general, macro scale of continued growth of pharmaceutical prescriptions.

According to the data,[1] which I have reviewed extensively with statisticians and economists, the average insured American purchases ten to thirteen different prescriptions per year. Over 10 percent of all Americans, and 50 percent of those over forty-five years of age, are buying cholesterol-lowering drugs, a number comparable to that for antihypertensives. The growth rate in users of chronic treatments has been and is conservatively projected to be over 10 percent per year, and the total number of pills taken grows 3 percent per year (Express Scripts 2007). Antidepressant use, despite negative publicity on suicidal side effects, is projected to increase 5 percent a year, and the rates of use remained steady in children even where such drugs were more or less banned. Stimulants, especially attention-deficit drugs, are growing 15 percent per year overall and 30 percent per year among those under nineteen years old. The scale of the market in prescription drugs is $500 billion per year. This does not include over-the-counter drugs, vitamins, nutraceuticals, alternative medicines, and so on.[2] The challenge is to account for the sheer amount of drugs being consumed and the mechanisms of their continued growth.

The numbers arrest me, even if I don't know how to believe them. What has abducted my interest is the problem of accumulation—the state of biochemical accumulation in the bodies of Americans continues at a rate that seems unbelievable, absurd, and unsustainable. At the center of the prescription growth in the United States are clinical trials as the key modality for determining facts about health and treatment, and guidelines that use those trials to redefine illness as a threshold. In this manner, health is reframed in the way that Goizueta reframed the potential consumability of soft drinks as something that can be grown in a virtually unlimited manner.

> "We want to recommend more aggressive treatment to people who are at very high risk," said Dr. James I. Cleeman, the coordinator of the group that issued the guidelines, the "National Cholesterol Education Program" of the National Heart, Lung and Blood Institute.
>
> "And," he added, paraphrasing Shakespeare, "there are more of them out there than are dreamt of in your philosophy." (Kolata 2001, 1)

Tseng Proof • 2011.10.17 07:41 8968 Rajan • Lively Capital • Sheet 56 of 506

PROOF

Cleeman's suggestion is that clinical-trial implications exceed not only what one thinks, but also one's very imagination. To imply a failure of imagination is to propose a need to reframe the problem. The people-at-risk (patients-in-waiting), he intimates, are not visible, even to themselves.[3] If Americans want to be healthy in the future, they must necessarily trust clinical trials and treat the numbers that they propose. Cleeman is talking about guidelines, introduced in 2001, which lowered the recommended level of bad cholesterol, thus tripling the number of people defined as high risk. Within his declaration is an order of reality in which epistemology (where clinical trials redefine high risk) determines that people who fall into the newly identified category *are* now ontologically at high risk, and being at high risk, they should (as in need to, ethically, imperatively) be put on treatment. Even as Cleeman pronounced these words, though, new clinical trials were under way that three years later, in 2004, would take the undreamed of numbers of people he referred to in 2001 and triple *them*, to 200 million. And in 2006 the thresholds were lowered even further.[4]

In a paragraph taken from an article in the *Wall Street Journal* published in 2004, the author emphasizes a set of population statistics that intensify an argument about the dangers of not listening to doctors and clinical-trial data: "Only a fraction of people with high cholesterol are on statins, despite a barrage of drug-company advertising backed up by guidance from public-health officials. About 11 million Americans currently take one of the statins, while some public-health experts say that at least 36 million should probably be on one. Globally, the discrepancy is even more dramatic: About 25 million are taking the pills while an estimated 200 million meet guidelines for treatment" (Winslow 2004, 1). The new target number, of 200 million people worldwide, represented one out of every thirty persons on the planet.

Universal screening programs and mass pharmaceutical regimes continue to regularly appear in the news, with the line between good use and abuse being increasingly hard to draw. The twenty-first century has already seen recommendations for mandatory cholesterol screening starting at age twenty for all Americans and for prescribing standard pharmaceutical treatments for the approximately 30 percent of the population expected to be at high risk when tested. Children are subject to screening for obesity and other risk factors for heart disease in similar ways. Each of these screens works by setting a number, a threshold, which, when crossed, triggers a diagnosis of risk or disease and a recommendation for treatment. Underlying the controversies surrounding mammograms, PSA prostate-cancer tests, and other screens is a concern as to whether, in light of evidence sug-

Tseng Proof • 2011.10.17 07:41 8968 Rajan • Lively Capital • Sheet 57 of 506

PROOF

gesting that lower thresholds might help more people, there could be *any reason* not to make the test more sensitive.

Looking at the growth rates and the projected rates of growth, I am confused. How does "our" pill-taking continue to grow? My conversations with colleagues, doctors, and economists invariably end with the interim conclusion that an ever-increasing prescription rate makes no sense. However, despite actively looking for projections that prescription rates will taper off in the future, I cannot find them. Instead, rates are predicted to grow 8–15 percent per year. While the number of prescriptions must surely, logically, stop growing at some point, it seems there are other logics at work.

Rereading Marx, I heard echoes of this pharmaceutical logic, where increases in productivity paradoxically create more work: "Hence, too, the economic paradox, that [machinery,] the most powerful instrument for shortening labour-time, becomes the most unfailing means for placing every moment of the labourer's time and that of his family, at the disposal of the capitalist for the purpose of expanding the value of his capital" (Marx 1976 [1867]). Could it be that health has become expandable? Doctors, government health officials, pharma marketers, all pronounce the most mystical, teleological sentences, as if they were channeling Marx about an infinite imperative for accumulation, substituting pharmaceuticals in the body for hours of labor: "We want to maximize the number of new prescriptions"; "We want to identify people at risk at the earliest possible point."

Marketers want to maximize the number of prescriptions in order to maximize profits. They see clinical trials as investments whose purpose is to increase sales of medicines: "Important clinical studies to conduct from a scientific or medical perspective are sometimes not important studies to conduct from a drug development perspective" (Spilker 1989, 372). Pharmaceutical researchers openly express their unhealthy predicament: "One of the significant problems for the Pharma industry is that of the 400 disease entities identified, only 40 are commercially attractive by today's requirements of return on investment" (Bartfai and Lees 2006, 14). They see patients as points of resistance: "Pharma's New Enemy: Clean Living" (title on cover of *Forbes*, 29 November 2004).

Just substitute a few words and these marketers and researchers could be quoting *Capital*. This is not surprising, for Marx was, after all, quoting the industrialists of his day. What has shifted are the terms: it is Illness as Value that is now being maximized, and the Health of Patients rather than their Labor that is being exploited. There is a parallel in form: perhaps marketers

Tseng Proof • 2011.10.17 07:41 8968 Rajan • Lively Capital • Sheet 58 of 506

PROOF

see unproductive health the ways capitalists saw unproductive labor. That is, marketers may see clinical trials as investments that increase the extent and intensity of prescriptions the way capitalists saw machinery as an investment that increased the extent and intensity of labor hours. The grammar and logic of capitalists that Marx studied in *Capital*, in other words, seem to be mirrored by strategies of pharmaceutical executives and marketers.

Step-by-step, the logic is impeccable. Everyone agrees with the basic points and the underlying framework: first, since medicine is so expensive, pharmaceutical companies are required to fund much of the research; second, as companies, they must of course be able to earn a return on these "investments." This framework is not scandalous. If the analogy holds, then it makes clear a strange dynamic: health as a growth field through treatments; surplus health growth via clinical trials. Mickey Smith, the author of a dozen classic works on pharmaceutical marketing, describes this indefinite resource of health as growth. "For as long as everyone is destined to die from some cause, a decline in one can only come at the expense of an increase in another. This is an inescapable truth, yet there seems to be some failure to recognize it. What society, and the pharmaceutical industry to some degree, is doing is making conscious or unconscious decisions about 'tolerable' causes of death" (Smith, Kolassa, Perkins, and Siecker 2002, 32).

Smith is pointing out that if health is defined as reducing risk, then health is an infinite phenomenon, since for every risk you reduce or eliminate, you still have a 100 percent risk of dying from something else. The limit to health research is not, then, a realizable healthy body, but a risk-free body, which instigates a virtually infinite process. There is always room for another study and another treatment, until patients can't take any more treatment due to side-effects, costs, or effort. To put this back in Coca-Cola terms, where Goizueta took the prospective soft-drink market from a measure of people's desires for Coke to the limit of their *capacity* to consume liquid, pharmaceutical companies have redefined health from a measure of symptom reduction to the limit of our body's *capacity* to consume treatments. How many drugs could we be mandated to take?

It looks therefore as if pharmaceutical companies have found a way to grow health through clinical trials, redefining health as treatment, in part by expropriating the means of diagnosing illness, through screening tests that tell us and the doctor that we need treatment. Consequently, the interests of the pharmaceutical industry lie not in reducing treatments, but in increasing them. No matter how obvious this might seem now, I didn't immediately

Tseng Proof • 2011.10.17 07:41 8968 Rajan • Lively Capital • Sheet 59 of 506

PROOF

see the connections, even when pharmaceutical researchers said it directly: "No one is thinking about the patients, just market share" (Bartfai and Lees 2006, 73).

The dilemma might be summarized this way: clinical trials are by and large conducted in order to test new treatments for healing a disease state or reducing the risk of future disease. Clinical trials designed to *reduce* the amount of medication people take and still save lives sounds like a win-win solution—the company will have a better, more targeted drug to sell, and people will get better faster—but in practice this kind of trial is remarkably rare, even counterintuitive. If successful, such a trial would remove a large number of people from a risk category, essentially assuring them that they had less risk than they had thought, and the drugs they had been taking for health would no longer be understood to provide such. As I have talked with doctors as part of my fieldwork, they, too, have registered a sense of how odd this dilemma is. Most trials are set up so that either they are successful and a new, more intensive treatment regimen is indicated, or they fail and the status quo prevails. Only the trials that backfire and find excessive side effects result in reduced treatment. Doctors are particularly struck by how easy it is to put people on medication because they meet guideline criteria and how difficult it is to get them off. There are often no studies conducted to determine when it would be better or safer to stop giving a medication to a patient, while at the same time there are very few studies of the long-term effectiveness or safety of those medications (Klein et al. 2002). Such studies do not interest drug companies, because, again, they could conceivably shrink the market for treatments. The general trend, therefore, is for the industry to conduct only trials that would grow the market by increasing the amount of medication in our collective lives, and the empirical data for U.S. pharmaceutical consumption bears this out.

run The_BioMarx_Experiment.prog in all [marx.works]: replace [Capital] with [Biomedicine]

Marx's categorical analysis seeks to explain some of the apparent anomalies of modern social life as intrinsic aspects of its structuring social forms: the continued production of poverty in the midst of plenty, the apparently paradoxical effects of labor-saving and time-saving technology on the organization of labor and social time, and the degree to which social life is controlled by abstract and impersonal forces despite the growing potential ability of people to control their social and natural environment.
MOISHE POSTONE, *TIME, LABOR, AND SOCIAL DOMINATION*

Tseng Proof • 2011.10.17 07:41 8968 Rajan • Lively Capital • Sheet 60 of 506

PROOF

Rereading *Capital*, I found what I felt to be remarkable parallels between the pharmaceutical growth process and especially the chapters on machinery. Machinery both multiplied labor power and therefore seemed to be a reason to labor less, and yet in the industrial system, it had the paradoxical effect of increasing the amount of labor needed, in order to continue to produce surplus labor. Theoretically this was worth pursuing. Thus, in order to better understand the pharmaceutical industry and the logic and political economy of treatment maximization, I have conducted an experiment: I have attempted to channel Marx, twenty-first century Marx, using twenty-first century technology. Karl BioMarx is the author of a future automatic translation of *Capital* into *Biomedicine*.[5] I use *biomedicine* as the general term because I think this analysis has relevance to the broad set of health industries that are science, statistical, information-based, and for-profit.

Methodologically, Marx operates with a fascinating strategy: he reads newspapers, government reports, factory guidelines, and economists. One of the analytic tactics he deploys regularly is to point to how much of what he would like to say as *critique* has already been said *openly*, in public and in reports, by capitalists. That is, exposé alone is not critique; one must show how the system reinforces its worst tendencies despite being conscious of them. Furthermore, most of what Marx found scandalous had been publicly scandalous at the time it was first being perpetrated. Yet critique and scandal had been assimilated, naturalized, and their very scandalousness and systematicity had been forgotten. What makes it hard to keep the intolerable nature of a particular phenomenon in focus is twofold: first, economists cover it up with logical explanations; second, capitalists and workers may perceive many aspects of it to be necessary and even desired, but still consider it to be in need of tweaking. Indeed, Marx himself notes that he is not claiming that capitalist system, for all of its horrors, is worse than what went on before—only that it needs considerable improvement.

For this chapter, I checked out a number of pharmaceutical-industry textbooks from the University of California libraries. Written by pharmaceutical researchers and marketers, as well as by management consultants who work for or have worked for pharmaceutical companies, these books are intended to teach readers about the workings of the pharmaceutical industry. They are practical, orienting books. They include *Drug Discovery: From Bedside to Wallstreet* (2006), by Tamas Bartfai, a long-time pharmaceutical researcher at Hoffman la Roche and now chair and professor of neuropharmacology at Scripps Research Institute, and Graham V. Lees, a scientific editor and publisher; *The New Medicines: How Drugs Are Created, Approved, Marketed, and*

Tseng Proof • 2011.10.17 07:41 8968 Rajan • Lively Capital • Sheet 61 of 506

PROOF

Sold (2006), by the researcher Bernice Schacter; and *A Healthy Business: A Guide to the Global Pharmaceutical Industry* (2001), by Mark Greener. They are concerned, above all, with helping scientists and laypersons understand *how* it matters that pharmaceutical research and sales is always a business.

With this in mind, I used an electronic copy of *Capital* (from the Marxists Internet Archive, www.marxists.org) and began to systematically substitute key words. The aim was to create a theoretical fission between contemporary healthcare shifts and nineteenth-century industrial shifts. What became immediately apparent was how careful a writer Marx was. Systematic substitution actually works. After many attempts to find an appropriate program of substitutions, the result is a text in which many of the sentences seem uncannily prescient, and many more present surprising and challenging formulations.

I treat this as an experiment. It is ongoing. The words I've come to select are quite specific to the logic of surplus health and derived through interaction with the pharmaceutical marketing literature. In this substitution, *value* becomes *illness*, *machinery* becomes *clinical trial*, *employment* becomes *treatment*, and so on. What this produces is an experimental logic of medical growth through increased diagnosis and the magic of symptom-fetishism.[6] An examination of the passages that use the substitute terms helps one think through possible articulations of how thresholds work in patients and for biomedical growth, and how the system of biomedicine has logics that easily outstrip local analysis of pharmaceutical action.[7] This chapter is a preliminary read through some of the consequences of *Biomedicine* alongside some passages from my forthcoming book.[8]

My pocket origin story of this biomedical form of capital is as follows: it could be said to start when medicine as an arm of capital (charged with maintaining workers for work) became an industry itself, beginning in the 1930s and picking up steam after the Second World War. The healthcare industry has its own imperatives for growth that on the face of it are contradictory to capital; that is, healthcare grows by treating more illnesses, yet it should not remove workers from the workplace. The solution is to appropriate that part of health that is not needed for work. This surplus health includes those persons who are too young or too old to work, and it includes illnesses that can be treated "on-the-job," so to speak, without keeping the worker from working. The latter encompasses both illnesses of the everyday (like mild depression) and illnesses of the future (like risk factors and symptomless illnesses like cholesterol). Each of these areas of illness can easily be shown to be major targets of diagnostic and therapeutic development, and

Tseng Proof • 2011.10.17 07:41 8968 Rajan • Lively Capital • Sheet 62 of 506

PROOF

each has had phenomenal growth in the last fifty years, intensifying especially in the last decade.[9]

Comparing pharmaceutical textbooks with *Biomedicine* has allowed me to explore the ways in which mass medicine functions as a regime of capital, and hopefully to better understand why medicine continues to be developed in such promising ways (more knowledge of health and illness, and more treatments) that are nonetheless tragic (we are taking more medicines, and not necessarily dying less). Working through BioMarx alongside contemporary writings also helped me understand more about how Marx struggled to make sense of the capitalists of his day. Moreover, the uncanny prescience of BioMarx provides insight into the strange ways in which pharmaceutical analysts talk about health. In the conclusion I will discuss more about my relation to Marx and our relation to the logic of biomedicine. In the meantime, I will walk through this logic, learning how pharmaceutical companies have come to see the population. Perhaps it will also become evident how the public has come to accept a notion of quantitative health, as investment, and how this might not lead to the best future.

replace all [commodit(y/ies)] with [Symptom(/s)]

Where *Capital* begins with a discussion of the commodity, *Biomedicine* begins with the symptom, and this allows us to see how strange health and illness have become.

> The Healthy Life of those societies in which the Biomedical mode of Medicalization prevails, presents itself as "an immense accumulation of Symptoms," its unit being a single Symptom. Our investigation must therefore begin with the analysis of a Symptom.
>
> Felt-Illness become a reality only by use or Healing: they also constitute the substance of all Healthy Life, whatever may be the social form of that Healthy Life. In the form of society we are about to consider, they are, in addition, the material depositories of Measured-Illness.
>
> As Felt-Illness, Symptoms are, above all, of different qualities, but as Measured-Illnesss they are merely different quantities, and consequently do not contain an atom of Felt-Illness. (C1: ch. 1)

The distinction described here is between, on the one hand, experiencing Felt-Illness (feeling sick) and going to the doctor to change how you feel, and, on the other hand, watching an advertisement or getting screened

Tseng Proof • 2011.10.17 07:41 8968 Rajan • Lively Capital • Sheet 63 of 506

PROOF

(measuring your illness) and being told you may be at risk and should talk to your doctor about possible treatments. In this substitution, symptom is shown to be two-sided in the way that Marx showed the commodity to be two-sided. It had both a use value and an exchange value. The exchange value renders the commodity quantitatively comparable to every other commodity. With biomedicine, we see a similar shiftiness. A symptom seems to be both felt and measured. As measured, the symptom begins to take on a life of its own. A screening test for high cholesterol tells us we have been ill without knowing it, and we begin to experience ourselves as *having high cholesterol*. Or a test suggests we have a high risk for prostate cancer and we feel the need to do something. Even a question may suggest that though we think we feel fine, we *actually feel ill* without knowing it. For example, here is a transcript of an early unbranded commercial by Lilly to help promote Prozac.

> VOICE-OVER: Have you stopped doing things you used to enjoy? Are you sleeping too much, are you sleeping too little? Have you noticed a change in your appetite? Is it hard to concentrate? Do you feel sad almost every day? Do you sometimes feel that life may not be worth living?
> VOICE-OVER: These can be signs of clinical depression, a real illness, with real causes.
> SCREEN-TITLE: Depression strikes one in eight
> VOICE-OVER: But there is hope, you can
> SCREEN-TITLE: Get your life back
> VOICE-OVER: Treatment that has worked for millions is available from your doctor. This is the number to call for a free confidential information kit, including a personal symptoms checklist, that can make it easier to talk with a doctor about how you're feeling. Make the call now, for yourself or someone you care about.

This direct-to-consumer (DTC) television commercial begins as a checklist in the form of an interrogation, with simple questions that are very general: are you sleeping too much or too little? But the seriousness of the questions is contained in the follow-up: "These can be signs of clinical depression." This conclusion converts the questions into a medical algorithm, a logical process following a series of steps. The checklist of symptom questions *measures* your potential illness. But the grammar arrests: "These can be signs" is a peculiar phrase. It is retroactively transformative, inscribing aspects of one's life as symptoms. What you had previously thought of—if at all—as personal variations in mood and habit are brought into heightened aware-

Tseng Proof • 2011.10.17 07:41 8968 Rajan • Lively Capital • Sheet 64 of 506

PROOF

ness; if you had not considered them to be symptoms, now you might. The first implication is that you are, maybe, suffering from a serious disease and do not know it. But this is not a presymptomatic form of awareness. Unlike the situation in Nelkin's and Tancredi's *Dangerous Diagnostics* (1989), where a brainscan or genetic test reveals a disease before it manifests symptoms, here you find out that you have been suffering from symptoms without knowing it.

The grammar of the phrase "These can be signs of X" or "You could be suffering from X" are not simple performatives (see Austin 1962). They do not assert that you *have* depression, nor do they diagnose. For legal, marketing, and health reasons, the grammar is explicitly modalized as possibility: "These *can* be," "You *could* be," "You *might* be." But such suggestions do give you a new potential. You cannot, morally, ignore the possibilities they raise, because your status has changed via this information. You really might *be* suffering (see Sacks and Jefferson 1992). You are *now* at risk (for being at risk), you now *know* that you have been at risk, you *have* to try to do something about it. And the commercial draws you out with "There is hope." Why is there hope? Because treatments are available.

The dynamic here shifts symptoms away from being *felt* toward being *measurements* controlled by others. Even though you self-diagnose, you do so via an algorithm, converting your embodiment into quantitative signs. Where Marx described the odd situation of the worker who must be free to choose to work, but nevertheless must work, BioMarx details the parallel requirement that a person must both be free to accept a diagnosis and yet is obliged to accept it.

> The Patient instead of being in the position to Submit Symptoms in which his Health is incorporated, must be obliged to offer for Submission as a Symptom that very Healthiness, which exists only in his living self.
>
> For the conversion of his Test-Scores into Biomedicine, therefore, the Diagnoser of Test-Scores must meet in the market with the Fearful Patient, Fearful in the double sense, that as a Fearful man he can dispose of his Healthiness as his own Symptom, and that on the other hand he has no other Symptom for Submission, is short of everything necessary for the realisation of his Healthiness. (C1: ch. 6)

The dynamic goes as follows. A person watches a commercial and goes to a doctor, or gets screened and finds out she has a risk factor. She is supposed to take action to reduce it: change her lifestyle or take a pill. This is

Tseng Proof • 2011.10.17 07:41 8968 Rajan • Lively Capital • Sheet 65 of 506

PROOF

for her health, here defined not in terms of illnesses whose suffering she feels, but in terms of a measure whose threshold she has crossed. By taking the treatment she reduces her risk, and this generates health in herself. This health, on should note, is based entirely on clinical trials whose facts have set the guidelines that determine her risk. Felt illness still exists—those times when her body drives her to see a doctor—but more and more of her "illnesses" are detected only through measurements, checklists, and biomarkers. These measures are her symptoms, which she fearfully and proudly tries to reduce. As one patient shouts to the world in a commercial: "I've lowered my cholesterol!"

From a marketer's point of view, the question is how to get you to add depression, breast cancer, cholesterol to *your* lived anxieties, to your personal agenda, enough so that you attend to it, find more information, and talk to your doctor about it.[10] The problem marketers must solve is how to get their particular facts into your head as facts that you come to depend on. For instance, another commercial begins with a scene of middle-aged people on exercise bikes in a gym, working out but looking tired. The only sound is of a ball rolling around, and superimposed above the exercisers is a spinning set of numbers. Finally the ball is heard dropping into place; the number is 265. The cholesterol roulette is over. The text on the screen: "Like your odds? Get checked for cholesterol. Pfizer."

The form of such commercials draws on a public-health logic of awareness: the unaware consumer-at-risk must be made into a patient-in-waiting. In order to achiever this, the consumer's felt-sense of health must be attacked as not simply mistaken, but dangerous. A campaign for colorectal cancer exemplifies this, first asking, "Are you the picture of health?," then warning, "You may look and feel fine, but you need to get the inside story."[11]

> Once adopted into the Medicalization process of Biomedicine, the means of Health passes through different metamorphoses, whose culmination is the Threshold, or rather, an automatic system of the Clinical Trial . . . so that the Patients themselves are cast merely as its conscious linkages. In the Threshold, and even more in the Clinical Trial as an automatic system, the Felt Illness, i.e. the Body quality of the means of Health, is transformed into an existence adequate to fixed Biomedicine and to Biomedicine as such; . . . it is the Threshold which possesses skill and strength in place of the Patient, is itself the virtuoso, with a soul of its own in the mechanical laws acting through it. . . . The Patient's activity, reduced to a mere abstraction of activity, is determined and regulated on all sides by

Tseng Proof • 2011.10.17 07:41 8968 Rajan • Lively Capital • Sheet 66 of 506

PROOF

> the movement of the Clinical Trial, and not the opposite. The science . . . does not exist in the Patient's consciousness, but rather acts upon him through the Threshold as an alien power, as the power of the Threshold itself. The appropriation of living Health by objectified Health.[12]

The process described here is the turning over the state of your health-in-general or healthiness to biomedicine so that it is something you *must* look up; it is fully expropriated from your own experiences, since you can't trust your senses, even though "you may look and feel fine." In turn, you come to experience *risk itself*. "Lipitor caught everyone by surprise since it did not have competitive outcomes data, but it shifted what counted as success beyond long-term clinical trials (hope) to short-term biomarker reductions (signal, as in lowered cholesterol numbers), which in turn became experiencible" (Moss 2007, 31).

Converting hope into a signal, a biomarker (cholesterol) that becomes a type of felt-illness (experiencible) completes the transformation of measured illness into the two-sided symptom that takes on a life of its own. BioMarx calls this symptom-fetishism, where the number becomes embodied. Risk is more real than lived healthiness. The question is thus: how did measured illness and risk come to be the definition of health?

replace all [Cooperation] with [Preventive Health]

The shift to measured illness took place during the twentieth century, at the intersection of public health and clinical studies, as *preventive health*. Public health recognized that some illnesses needed to be treated collectively in order to prevent repeated outbreaks. Vaccinations are the prototype. Large-scale clinical studies, beginning in the 1950s, approached illnesses collectively even if they were not spread like infectious diseases. The Framingham Heart Study was foundational as a prospective (future-oriented) study that examined the health of over five thousand people in Framingham, Massachusetts, over their lifetimes and eventually across three generations. It aimed to discover connections between ongoing behaviors (like smoking) or biomarkers (like cholesterol) and future events (like heart attacks).

Clinical studies like the large-scale Framingham Heart Study enabled pioneers in epidemiological medicine like Geoffrey Rose to articulate the need for a comprehensive notion of "preventive health." In his now classic treatise, *Strategies for Prevention* (1993), Rose described how large-scale studies slowly transformed our definition of health from the traditional,

Tseng Proof • 2011.10.17 07:41 8968 Rajan • Lively Capital • Sheet 67 of 506

PROOF

simple models of disease—in which the patient first suffers, then calls on the doctor—to an epidemiological, measured model of diseases like hypertension and high cholesterol. These represented "a type of disease not hitherto recognized in medicine in which the defect is quantitative not qualitative" (Pickering 1968, in Rose, Khaw, and Marmot 2008, 7). Rose describes the traditional model of diseases as one of felt-illness, whose treatment aims at removing the felt-illness. The quantitative model, however, is one of measured deviance, whose treatment aims at reducing the risk of future adverse events.

The most significant difference between these two models is in the form of diagnosis as we move away from "Has he got it?" to "How much of it does he have?" (Brayne and Calloway 1988, quoted in Rose, Khaw, and Marmot 2008, 9). Given a continuum of measurements (blood pressure tends to be shaped like a bell curve in populations), Rose asks where the diagnostic line should be drawn. Our current administrative medical system demands clear decisions; "this decision taking underlies the process we choose to call 'diagnosis,' but what it really means is that we are diagnosing 'a case for treatment,' and not a disease entity" (Rose, Khaw, and Marmot 2008, 10). In other words, given the continuum of scores where everyone has some blood pressure, the only meaningful reason to draw a line is because that line makes a difference in what we do about it. Rose's public-health perspective allows him to see and state clearly consequence of quantitative disease models, that *diagnosis equals treatment*.

Rose's argument thus tracks that of chapter 13 of *Capital*, on "Cooperation," in which Marx examines how man's collective labor is much more productive than the sum of individual efforts—it becomes social labor. Rose, in turn, offers the concept of population illness. Rose shows how important it is to consider many illnesses, like hypertension, as population illnesses, requiring population-based treatments. To study population illnesses though, for which the actual events (like heart attacks or deaths) are rare, one needs to run very large clinical studies. In one kind of clinical study, the *clinical trial*, the population being studied is randomized at the beginning into often two groups, with one being given a specific treatment, like a drug, and the other group being given a placebo or a competitor treatment. Clinical trials study the effect of a treatment on a large group of people over a period of time (two weeks to ten years), and it is the large scale of the trial that allows a small treatment effect to be multiplied enough to be visible. For example, it might require a trial of ten thousand people over the age of thirty taking a beta-blocker for more than five years to determine

Tseng Proof • 2011.10.17 07:41 8968 Rajan • Lively Capital • Sheet 68 of 506

PROOF

whether the risk of a heart attack has been reduced by that particular treatment. If ten fewer fatal heart attacks are found (forty among the five thousand taking the drug versus fifty among those not), then the study might reach statistical significance and be used to get FDA approval for the drug.

If the trial is well-designed, its result then becomes a type of public-health fact. If you are over thirty and take the pill every day for five years, you reduce your chances of a heart attack by 20 percent (this is a big percentage, as the original chances of having a heart attack was 1 percent, but and is now reduced to 0.8 percent). Of course, another way to look at it is that 500 people must take pills every day for five years in order to prevent one heart attack; the number needed to treat (NNT) is therefore 500. Of those people, 495 would not have had heart attacks in any case, and four of them would have had heart attacks despite taking the pill. Thus there is a lot of unnecessary treatment (another way to think of that NNT). This kind of result is known as the "prevention paradox" in which "many people must take precautions in order to prevent illness in only a few" (G. A. Rose 1992, 12).

Rose's analyses were hailed as critical insights that reformulated how to treat coronary heart health and which brought public health and clinical medicine back together. Rose uses the word *precautions* because treatments for him mean lifestyle, diet, and behavioral changes first, and he displays extreme caution regarding prescriptions, since he points out that large NNTs greatly amplify the number of long-term side-effects, many of which would be all but impossible to detect without other massive, long-term, and prohibitively expensive clinical trials.

replace all [value(s)] with [Illness(es)]
replace all [labor] with [Health]

Rose's book is fascinating because it clearly demonstrates how preventive logic based on clinical trials does not have to result in more medicine. Rose is acutely aware, however, that it could. I have dwelled on Rose's arguments for preventive medicine not only because they've been persuasive in policy and research, but also because they show the true power, insight, and innovation of population (or mass) health. Since he literally marks off population health from traditional felt-illness, he provides an image of measured, quantitative disease that is not economically beneficial, but is plausible and rational on humanitarian grounds. Rose in fact begins his book with a meditation on the *uneconomic* consequences of preventive health, noting that it does not save the state money, since it tends only to postpone, rather than

Tseng Proof • 2011.10.17 07:41 8968 Rajan • Lively Capital • Sheet 69 of 506

PROOF

truly prevent health problems. He also points out that the longer one lives, the more treatments one tends to require. In the end, Rose argues for preventive medicine solely on humanitarian grounds, that more life with less illness is better.

Though he hints at the fact that preventive health has no inherent limit and that thresholds of treatment must be carefully and socially debated, Rose does not confront or even consider the use of clinical trials and preventive-medicine logic by for-profit pharmaceutical companies. The shift from clinical trials primarily for health to clinical trials for profit has been taking place in pharmaceutical companies since the 1950s (Greene 2006). The historian Steve Sturdy summarizes the process:

> The scene was set for the rapid institutionalization of clinical trial procedures in the postwar years. Drug companies, government agencies and charitable organizations now realized that, by exerting strict controls over the supply of new drugs, they could force clinicians to participate in standardized clinical trials. But at the same time, clinicians came to recognize that they too could benefit from participating in such trials. The development of dramatically effective new drugs, including the antibiotics and subsequently such molecules as cortisone (Cantor 1992; Marks 1992), did much to raise public expectations of the power of modern medicine. By acting as gatekeepers to potentially beneficial new therapies, clinicians could do much to enhance their own professional prestige and authority over patients. As a result, large scale clinical trials became one of the defining features of the postwar medical landscape. Drug companies and administrative bodies were now able to conduct large scale clinical experiments to measure the therapeutic effects of a wide range of novel substances. . . . Doctors had now ceded much of their clinical autonomy to the administrative demand for standardized forms of medical practice. (Sturdy 1998, 283)

The importance and centrality of prevention and clinical trials for advancing healthiness is disputed by no one. Current spending on clinical trials exceeds $14 billion per year. According to governmental and nongovernmental studies, in 2004 around 50,000 clinical trials took place in the United States, involving 850,000 people in industry-funded preapproval testing, and another 725,000 in postmarketing (Phase IV) trials. In addition, 750,000 more people participated in government-funded trials. While these numbers may seem large, within the health industry they represent a crisis of under-enrollment. Four out of every five clinical trials are delayed

Tseng Proof • 2011.10.17 07:41 8968 Rajan • Lively Capital • Sheet 70 of 506

PROOF

due to recruitment problems. "The number of trials has doubled in the past 10 years, forcing companies to seek trial participants in emerging markets outside of the saturated areas in the United States and Western Europe. Emerging markets such as India, China, and Russia offer drug companies a volume of potential subjects, and trials can often be executed at reduced costs" (Ernst and Young 2006). The pressure to rapidly complete clinical trials has led to doctors being paid to enroll their own patients, and in a number of countries, people participating as experimental subjects in exchange for healthcare.[13]

At the same time, the ever-increasing scale of clinical trials, the sheer number of them, and the size of each one has put them more or less out of even government's financial reach. Across the board, the pharmaceutical industry, government officials, and even critics agree that only corporate institutions have the resources to conduct most clinical trials. For example, in examining the Celebrex and Vioxx discussions at the Food and Drug Administration (FDA), the pharmaceutical researcher Bernice Schacter noted, "Lengthy discussion about what kind of trial or trials are needed to clarify the issue of the relative cardiovascular safety of the NSAIDS [nonsteroidal anti-inflammatory drugs], triggered both by the FDA's question and a suggestion by Dr. Robert Temple, Director of CDER's [Center for Drug Evaluation and Research's] Office of Medical Policy, that what he called an ALLHAT trial [Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial] be done to compare the cardiovascular effects of NSAIDS using naproxen and diclofenac as controls. Whether such a megatrial could be done and who would fund it remained unclear, though the enthusiasm among the members of the committee was high" (2006, 219). In other words, the proper questions that needed to be asked with regard to the drugs probably "could not" be investigated, since the clinical trial would be too expensive for government funding and since the direct-comparison questions would too risky for a pharmaceutical company to ask, given that corporate research funding is tied to investments.[14]

The problem is that biomedical companies are first and foremost companies; they exist to make profits, and therefore they must run clinical trials as *investments* whose purpose is to grow returns. This fact is the key form through which marketing takes over research design in pharmaceutical companies. The insight we get from BioMarx is that the return on investment is calculated not solely on labor of workers or clinical-trial subjects, but that value is seen to accrue from the patients via *treatment numbers* (even speculative ones). Hence clinical trials become machinery for generating

Tseng Proof • 2011.10.17 07:41 8968 Rajan • Lively Capital • Sheet 71 of 506

PROOF

evidence for generating prescriptions. In other words, the flipside of an evidence-based marketing strategy is that markets are made through evidence, and potential marketable evidence (from a clinical trial) is the determining factor in running the clinical trial in the first place.

The mystery of value for Marx lies in the fact that value is not in fact tied to material wealth; instead capitalists are fixated on labor as value. For the capitalist, the machinery, factory, raw materials, and distribution are all sunk costs, or "fixed capital." The only "variable capital" is the worker, whose full day of labor power the capitalist forces him to sell. If he could, the worker would sell his labor only dearly, but since there is no better work elsewhere and the workers is easily replaced, he must sell a whole day's labor in order to work at all. The wages the capitalist pays the worker is enough to allow him to survive and reproduce. After the worker has put in enough hours to cover his cost (and the cost of the fixed capital), everything else is *surplus labor* resulting in *surplus value*. Capital brings this into being by striving (through competition) to bring necessary labor time to a minimum (so as to maximize surplus labor time), and the result is science, but in a misshapen form.

> "Hence it posits the superfluous in growing measure as a condition—question of life or death—for the necessary."
>
> 1. capital "calls to life all the powers of science and of nature as of social combination and of social intercourse, in order to make the creation of wealth."
> 2. "on the other hand it wants to use labor time as the measuring rod for the giant social forces thereby created, and to confine them within the limits required to maintain the already created value as value." (1993 [1857]: 706)

Science and technology become tragedy because capital has a peculiar measuring system. Marx is quite clear that capitalism brings this science into being, but because it insists on labor as the measure of value, even when labor isn't necessary, it uses science and technology to produce more surplus labor, rather than to produce material wealth.[15]

In working with marketers and working through BioMarx's version of surplus, I have come to understand the pharmaceutical development process better. The pharmaceutical company sees the clinical trial, the pills, and marketing as sunk costs; the only variable capital is the total number of prescriptions (TRx) that are filled, which is the number of patients times the

Tseng Proof • 2011.10.17 07:41 8968 Rajan • Lively Capital • Sheet 72 of 506

PROOF

number of prescriptions they purchase. Health research therefore is measured by the number of projected total treatments.

Biomedicine thus calls to life the powers of science (though cooperation and social force) in order to create wellness, but

> on the other hand it wants to use Treatments as the measuring rod for those giant health forces, and confine them within the limits required to maintain the already created Health as Health. (BioMarx)

In other words, a pharmaceutical company thinks of health directly in terms of prescriptions, so that, as Rose concluded, treatments are the "meaning"—that is, use of—Health. Therefore a patient is valuable to pharma to the extent she takes treatments and continues to take them. A "healthy" person who is not on or does not like to be on medicine is, from the perspective of this economy, not valuable. In other words, from the perspective of value, healthiness is antithetical to biomedicine—only Health, abstracted and valorized, is valuable.[16]

Each clinical trial is evaluated first by whether and by how much profit it will generate for the company. Thus Bartfai and Lees take pains to spell out to their readers: "The company's order of priorities is extremely clear. The major factors in selection of a clinical candidate in the company's own priority order are: (1) marketing . . . (2) internal economics . . . (3) scientific, technical and legal issues . . . The regulatory and marketing groups, and then the clinicians, can always override scientific considerations; they 'call the shots.' . . . Under current circumstances this is unavoidable . . . Decisions of this caliber are so expensive and so delicate for the companies' future that they cannot be left to scientists and clinicians alone" (2006, 71–72). *Unavoidable* priorities. Companies are only doing what they have to do in order to survive. This is stated in the same manner as Marx: the executives, like the capitalists, are possessed by the circumstances. The result is that each clinical trial must be designed so that it increases the number of prescriptions purchased. It might seem that a steady state—keeping the population healthy and improving drug efficacy—would be enough to keep an industry alive, but the pressures on biomedicine to grow are enormous, leading to the need to accumulate prescriptions.

Marx described how "Capital as such has to grow" (G III:317). This accumulative sentiment pervades pharmaceutical industry discussion. "In order for Pharma and biotech companies to maintain double-digit growth rates through 2005, they need to multiply their productivity by a factor of five" (Perkins 2002, 148). Similarly, Mark Greener, a former research pharma-

Tseng Proof • 2011.10.17 07:41 8968 Rajan • Lively Capital • Sheet 73 of 506

PROOF

cologist and editor of *Pharmaceutical Times*, notes, "The stock market expects the pharmaceutical sector to grow at a healthy rate. A survey of 15 analysts in 2000 found that they expected the large pharmaceutical companies to grow between 12% and 15% per year between 2000 and 2005. They also expected sales to increase by between 8% and 10% each year, with the market increasing between 6% and 8% annually. However the U.S. market—the last unfettered, free pharmaceutical market—accounts for some 75% of growth worldwide, reflecting in part the impact of pricing controls" (Greener 2001, 36). Thus, not only is profit an unavoidable priority, but massive growth is too. The problem is precisely that pharmaceutical companies are *expected* to run clinical trials, and even critics like Jerome Kassirer, the former editor of the *Journal of the American Medical Association* (JAMA), concede that they *legitimately want profits* (Kassirer 2005, 188)

For Kassirer and many critics, the answer is better regulation in order to define ethical bounds for rule-binding the system to enable profitable pharmaceutical health. The fight between regulators and profits often leads to bizarre encounters, as described by Leonard Weber, healthcare consultant and former director of the Ethics Institute at the University of Detroit Mercy. "Drummond Rennie, a JAMA editor interviewed by Peter Jennings on Bitter Medicine 2002 agreed that drug companies 'are intent on keeping consumers on drugs, which are not as good as older drugs, for the simple requirement of profit.' 'Rennie responded yes, absolutely, and it would be strange if they didn't. "They've got to be prevented." Rennie's point was that the pharma industry needs to be understood as part of the for-profit business world . . . will do whatever they can in the pursuit of profits' limited only by legal restraints" (Weber 2006, 13). Although Weber goes on to suggest better business ethics, he leaves untouched the fundamental transformation of health value as measured by treatments. Indeed, better regulations would help curb the abuses, like withholding information on side-effects, but it does not address a deeper, structural concern, which is the dynamic shift that takes place when clinical trials are run by industry in order to grow itself.

replace all [machinery] with [Clinical Trials]

Increasingly, large companies need the mature sales . . . generated by several blockbusters—drugs that achieve sales of more than $1b annually—to fund R&D programmes and meet shareholders' expectations of growth.

MARK GREENER, *A HEALTHY BUSINESS*

Tseng Proof • 2011.10.17 07:41 8968 Rajan • Lively Capital • Sheet 74 of 506

PROOF

> A significant problem for the FDA is that there are too many me-too drugs submitted. . . . The companies see it as a way of generating profits, through establishing a new market share, and it is also seen as a safe way to introduce a new drug . . . [since the competition] has already validated the target. . . . But no one is thinking about the patients, just market share.
>
> TAMAS BARTFAI AND GRAHAM V. LEES, *DRUG DISCOVERY*

The *solution* to growth is clinical trials. They alone can increase the productivity of prescriptions, creating more drugs for more people for longer periods of time. Their dynamic in healthcare parallels that of machinery in capitalism. In *Capital,* machinery occupies a pivotal role, unleashing collective productivity and thus allowing one man working one hour to produce more than what two or ten or a hundred were able to produce without the machine. Machinery's paradox is the most tragic for Marx. The tremendous increase in productivity enabled by machinery would seem to liberate man from endless toil; with more wealth produced from less effort, it would seem to follow that less work would need to be done. But, historically, the opposite happened: machinery led to longer working days and required more workers, since capitalists came to see *not* using the machines as wasteful and therefore wanted them to be used at all possible times. Furthermore, machinery's relative ease of use meant that women and children could also be employed, expanding the labor pool tremendously and cheaply.

The analog in biomedicine has a similar paradox: clinical trials are an amazing way to increase the healthiness of the population. Although they have promised to reduce the amount of time we spend attending to our health, they have instead increased the time, energy, money, and treatments we apply to our health, and have extended treatment to children and the elderly in increasing numbers. This may seem overstated, but bear with me. Machinery under capitalism did increase productivity (and successful clinical trials do offer ways to increase healthiness), but capitalists employed machines not for that purpose, but instead to increase their profits. If a machine could save labor but would not increase profits, for example, then the capitalist would not use it. Marx discussed a case in England where women were sometimes used instead of horses for hauling barges because the women as "surplus population [were] beneath all calculation. Hence we nowhere find a more shameless squandering of human labor-power for despicable purposes than in England, the land of machinery" (C1:517). Cases like this, in which the decision to use a machine turns on whether it is "worth" it to replace humans, speak to the core of the labor theory of value. Increase

Tseng Proof • 2011.10.17 07:41 8968 Rajan • Lively Capital • Sheet 75 of 506

PROOF

productivity—but only if it does not cost more than employing labor and increases the surplus value of the remaining labor. Thus, only those machines which increased profits (e.g., by making a product that could be sold at a higher profit) would be installed.

The problem is eerily the same in biomedicine. "Today, 62% of the sales of Pharma is in the United States. But how many know that there are over 800 compounds that are sold in Europe, and which are highly efficacious, therapeutically wonderful, but which have not yet been registered in America? And they won't ever be. Because by now the patent life is so short, and the FDA so slow, that they cannot be. . . . [T]he marketers in the U.S. won't be interested. And it is nonnegotiable; this is how it is" (Bartfai and Lees 2006, 138). America as a pharmaceutical contradiction is all too familiar. Many critics echo Ken Silverstein (1999) in decrying a world where "millions [are spent] for Viagra, pennies for the poor." It may seem straightforward to hold drug companies responsible for the choices they make regarding which diseases to research, but as Bartfai and Lees indicate, this critique is internal to corporate logic. Almost every pharmaceutical industry textbook I found narrates an ongoing debate over precisely this issue, of whether a pharmaceutical company can afford to care about medicine and people, rather than about profits. Passing along this debate to future industry scientists is precisely the purpose of pharmaceutical industry textbooks in bringing it up. "Should they develop for this specific use and that one, but not the one unlikely to succeed or unlikely to generate a sufficiently large market?" (Schacter 2006, 116).

Especially today, under the pressure to maintain growth, apparently vile decisions are driven by a clear perception of "waste." One is literally "throwing money away" if one is not making "as much as one could" compared with other investments. "One of the significant problems for the Pharma industry is that of the 400 disease entities identified, only 40 are commercially attractive by today's requirements of return on investment. . . . Society needs to find a way to make more diseases commercially attractive if it wants Pharma investment in treating any of the other 350 diseases affecting hundreds of millions of people" (Bartfai and Lees, 2006, 14). Here Bartfai and Lees, a former pharma researcher and a publisher, seem to be calling for regulation to save them from their own structural violence. This call echoes an industrial practice, which Marx registers in a chilling footnote, wherein even kidnapping raids of children, who were forced to work in factories for more than twelve hours per day, were unstoppable as long as competition with other capitalists existed. One group of factories actually submitted a

Tseng Proof • 2011.10.17 07:41 8968 Rajan • Lively Capital • Sheet 76 of 506

PROOF

petition to the British government in 1863, pleading, "Much as we deplore the evils before mentioned, it would not be possible to prevent them by any scheme of agreement between the manufacturers. . . . Taking all these points into consideration, we have come to the conviction that some legislative enactment is wanted" (C1:297). Bartfai and Lees state that the question is not one of choices, but of structural pressure. Their mode is one of enlightened attack: it is society that needs to find ways to make thing better, to make unprofitable diseases profitable.[17] Similarly, Marx describes how under the regime of machinery, "Capital takes no account of the health and length of life of the worker, unless society forces it to do so" (C1:381).

Across the board, pharmaceutical-industry analysts are unabashed about these constraints and presuppositions. "Pharmaceutical companies tend not to invest in tropical medicines because they are unlikely to recoup their investments. . . . Given the pressure on pharmaceutical companies to maximize their return on investment, this attitude is unlikely to change without a major change in shareholders' attitudes" (Greener 2001, 122). This is what Marx was striving to explain about the interactions of Capital, how once you see it in process, then the entailments of that process have a type of force to them—not a deterministic force, but influential nonetheless. From inside the pharmaceutical industry, one feels that one's life is at stake, and certainly one's company is. The pressure from "other possible investments" (such as other disease research at the same company) is key, since this means that there does not even need to be competition from other companies for the process of value generation to exert its force. The very fact that disease research is an investment establishes an equivalence between investments, such that they become comparable along one dimension: quantitative health, or treatments.

> To the out-cry as to the physical and mental degradation, the premature death, the torture of over-Treatment, it answers: Ought these to trouble us since they increase our profits? But looking at things as a whole, all this does not, indeed, depend on the good or ill will of the individual Pharma. Free competition brings out the inherent laws of Pharma Experience, in the shape of external coercive laws having power over every individual Pharma. [82] (Ch. 10)

The problem of comparing possible treatment research within pharmaceutical companies is that saving one set of lives through research and development, marketing, and sales must be compared on return-on-investment profit grounds with saving other lives who may return more net profit.

Tseng Proof • 2011.10.17 07:41 8968 Rajan • Lively Capital • Sheet 77 of 506

PROOF

"Products that are not able to limp along must be eliminated. They are a drain on a business unit's financial and managerial resources, which can be used more profitably elsewhere" (Perkins 2002, 122). Most critics do not begrudge pharmaceutical companies this attitude, because they understand and have naturalized corporate funding of research.

Here is the twist so peculiar in capitalism and biomedicine: the company that one loves because it makes healing medicines becomes secondary (logically) to the money it returns. The disease one wants to cure becomes secondary to its market size. It comes to appear that it has to be this way. "Pharmacoeconomics plays a pivotal role. Drug development is very capital intensive and even big indications such as malaria and tuberculosis are affected. The cost means that small indications suffer, regardless of how good the science is. If drug discovery were a science-driven activity, one would expect scientists to be running drug companies. However, since Roy Vagelos of Merck retired [in 1995], no Big Pharma has been run by a scientist; they are all run by people who were trained in economics" (Bartfai and Lees 2006, 71). Bartfai and Lees suggest that because drug development is capital intensive, economic value comes naturally to supplant scientific or health value. The reason why this can be justified has its roots in Geoffrey Rose's insight that once disease comes to be defined as on a continuum with health, the only meaningful diagnosis is that which indicates treatment. Treatment therefore equates with diagnosis, and the market indicated by a diagnostic threshold is both a measure of profit and the very definition of "health." As health is an a priori "good," comparisons of two possible clinical trials turns on their relative profitability.

Inside a pharmaceutical company, this comparison is a source of continual negotiation, where clinical research directed at healthiness can clash with market research, leading to struggles over who should really be deciding clinical directions. Bert Spilker, the head of project coordination at Burroughs Wellcome and author of many pharmaceutical textbooks, writes of this struggle in his six-hundred-page *Multinational Drug Companies: Issues in Drug Discovery and Development*. Note how "medical value" retains only a ghost of its apparent persuasiveness: "The cooperation of research and development and marketing groups may be severely tested when an investigational drug has a high medical and low commercial value and the project draws resources (or would draw resources) away from projects that the marketing group believes have greater commercial value and are of high or medium medical value" (Spilker 1989, 427–28). There is a defensiveness in the qualifying phrase "of high or medium medical value," as if a me-too

Tseng Proof • 2011.10.17 07:41 8968 Rajan • Lively Capital • Sheet 78 of 506

PROOF

drug with low medical value would not be chosen no matter how commercially valuable it was.

Hidden (and assumed) within these debates over medical and commercial value is the fact that, like machinery, clinical trials seen from the point of view of investments become a different sort of beast than those seen from a medical point of view. The very innovative power of science and technology, productivity, and intensity comes to be transformed, mutated into profit and growth monsters. As Marx puts it, "This process of separation . . . is completed in large-scale industry, which makes science a potentiality for production which is distinct from labor and presses it into the service of capital" (C1:482). Similarly, Steve Morgan, Morris Barer, and Robert Evans, writing in 2000, eerily repeat the same insight: "Science and objectivity are of interest to a private, for-profit corporation only insofar as they further the quest for profits" (660). Looking closer at how clinical trials are implemented via BioMarx will let us see how surplus health continues to be expanded.

replace all [productivity] with [Knowledge]

> Using financial, contractual and legal means, drug manufacturers retain a degree of control over clinical research that is far greater than most members of the public (and, we suspect, many members of the research community) realize.
>
> STEVE MORGAN, MORRIS BARER, AND ROBERT EVANS,
> "HEALTH ECONOMISTS MEET THE FOURTH TEMPTER"

If growth is achieved through choosing to study those diseases that have the biggest markets, those markets can be stretched wider through choosing how to design clinical trials so they indicate more of the population for treatments. This is possible because clinical trials were designed to compare treatments for existing diagnoses that had known outcomes, such as cures. When clinical trials are used to define a diagnosis along a continuum, they turn out to be remarkably flexible. In *Rose's Strategy of Preventive Medicine* (2008), Geoffrey Rose uses as an example the potential benefits of serum-cholesterol reduction on coronary-heart-disease deaths. In a table—which I have reproduced here, since it makes clear just how open clinical trials can be—he breaks down risk by age and sex.

Rose points out how a screening program for men 55–64 would require 230 men to be screened and 100 of those screened to be treated for five years, and would prevent one death on average. And this, he says, "relative

Tseng Proof • 2011.10.17 07:41 8968 Rajan • Lively Capital • Sheet 79 of 506

PROOF

TABLE 1 Estimates of potential reduction in coronary heart disease deaths from screening for raised serum cholesterol (> 6.5 mmol/l) in different age and sex groups

Age in years	25–34	35–44	45–54	55–64
Percentage with raised level				
Men	20	35	40	45
Women	15	20	50	70
5-year deaths per 1,000 in this group				
Men	1.2	5.8	21.3	48.1
Women	0.2	1.1	4.5	15.9
*Number screened to prevent 1 death in 5 years**				
Men	21,100	2,500	600	230
Women	137,300	23,200	2,200	450
Number treated for 5 years to prevent 1 death				
Men	4,200	860	230	100
Women	20,600	4,560	1,100	320

*Assuming 20% reduction in deaths among all eligibles.
SOURCE: Based on Rose, Khaw, and Marmot 2008.

to other preventive or therapeutic measures . . . would be reckoned a good value" (Rose, Khaw, and Marmot 2008, 37). Among women 25–34, however, such a program would require screening 137,300 women and placing 20,600 of those screened on treatment for five years to prevent one death. The number needed to treat (NNT) is so high in this instance because that demographic has so few coronary deaths to begin with (only 0.2 per 1,000, or 1 in 5,000, over five years). Rose's response illuminates a crisis in health prevention. Despite appearing objective, one must engage in a relative valuing of lives: "Unless one takes the extreme and wholly unrealistic view that the saving of a life is worth any price at all, then it is hard to justify" (ibid.). Rose's need to increase the hyperbole, saying "extreme and wholly unrealistic," reveals the dilemma, since he is nonetheless talking about a program that would save lives.

Empirically, a clinical trial could be designed to show a population goal for putting everyone over twenty-five being on cholesterol-lowering drugs, despite the incredibly huge NNT. Which clinical trial to run, where to draw the line, is thus a social and political dilemma. The dilemma becomes a full-blown contradiction when one considers the structural economic constraints. First, only a few of the many possible population and cholesterol groups can be studied; and second, due to the large size of the groups and

Tseng Proof • 2011.10.17 07:41 8968 Rajan • Lively Capital • Sheet 80 of 506

PROOF

the expense of clinical trials, it is pharmaceutical companies who are allowed to choose the groups. Make no mistake, the clinical trial will generate legitimate and true facts about health; it will indicate treatment for whatever population subset it successfully studied. And since very few similar clinical trials are likely to be conducted, the facts generated by the first trial may very well be the *only* facts available about this kind of health.[18]

Now ask yourself: if you were running a pharmaceutical company and had to choose between a study that could show a high treatment benefit for men over forty-five, or one that would show a low benefit for (but still save lives among) everyone over twenty-five, which would you fund?

> As Pharma, he is only Biomedicine personified. His soul is the soul of Biomedicine. But Biomedicine has one single life impulse, the tendency to create Illness and surplus-Illness, to make its constant factor, the means of Medicalization, absorb the greatest possible amount of surplus-Health. (Ch. 10)

Since the problem for pharmaceutical companies is how to keep growing despite the constant pressure of stockholders, competitors, and the time-bombs of their own patents running out, clinical trials *must* be designed to maximize their markets in order to maximize their investment return. The point is that there is corporate awareness of the variety of possible clinical trials, and conscious selection of those trials that meet the desired profile (long-term, large population, etc.). Bernice Schacter's book, *The New Medicines*, written by a researcher to train future pharmaceutical researchers, explains the dilemma this way: "If the team elects to seek approval for a narrow subset of patients with a certain condition, then the market for the drug may be too small to make financial sense for the company. If they seek the widest use, for example, for everybody with arthritis, they are at a greater risk of failing to demonstrate safety and efficacy and therefore failing to get approval. This is based on biology" (115).

Here again one discerns the parallel to machinery in capitalism: machinery can only be implemented when it increases surplus value. In this admonition, Schacter makes clear why clinical trials cannot be designed with healthiness as a priority, why companies must see health as a *means* to profit through increasing treatments. And this is how clinical trials that result in larger NNTs (i.e., less efficient drugs) come to be valued more than smaller ones. The dynamic of surplus health is at work in the fact that the larger NNT means that more people will be taking the drug without benefitting from it, but since there aren't more facts available about who will actually benefit, it

Tseng Proof • 2011.10.17 07:41 8968 Rajan • Lively Capital • Sheet 81 of 506

PROOF

appears as if everyone taking the pill is benefitting a little by reducing their risk. "Ideally the study would look at the drug's effects on the so-called 'hard' endpoints—death or a heart attack, for example. However such studies tend to be large, expensive, and lengthy. So many studies rely on 'surrogate' endpoints. These predict the risk of suffering a hard endpoint either for each patient or from a population perspective. . . . Taken across the whole population these are associated with, for example, a risk of stroke asthma or heart attack. However that does not show that any particular patient will develop the disease" (Greener 2001, 61).

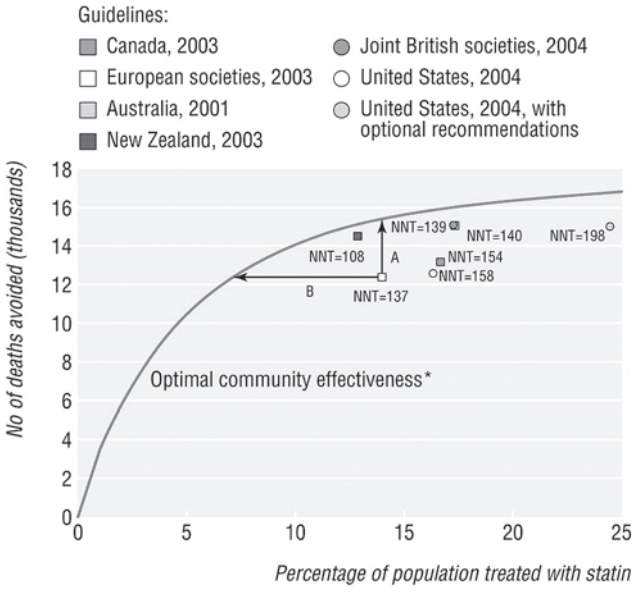
> In one word, surplus-Illness is convertible into Biomedicine solely because the surplus-Risk Diagnosis, whose Illness it is, already comprises the material elements of new Biomedicine. (BioMarx)

A recent article by D. G. Manuel et al. in the *British Medical Journal* comparing eight cholesterol treatment guidelines in four countries made this dynamic visible (see 1). The researchers designed a graph that mapped the population indicated by each of the guidelines and the lives that would be saved, assuming that the clinical-trial evidence was correct and the guidelines were scrupulously followed. The first thing to note about the graph is that different guideline committees in different countries and at different times made very different choices about how to implement the facts at their disposal. They came up with vastly different percentages of the population indicated for treatment and numbers of lives potentially saved. The curve on the graph is the researchers' extrapolation of the ideal treatment-to-saving rate. The fact that it is a curve and not a point shows something very important about the graph as a whole. Any point under the curve is a potential guideline. And any point would save lives. The graph thus illustrates that there are thousands of potential clinical trials that could be run and thousands of consequent treatment indications.

In order to compare the different guidelines, the authors describe the horizontal distance from the curve for each guideline as the efficiency gap, which implies that the same number of lives could be saved while treating fewer patients. The vertical distance to the line they call the efficacy gap: how many more lives could be saved with a different guideline targeting the same percentage of the population. They thus suggest that prudent committees design clinical trials and guidelines to move the points up and to the left. Yet such trials would be predicated on decreasing the numbers of people on medication. Like Rose, these researchers fail to consider the countervailing pressure of companies, for whom the value of a clinical trial

Tseng Proof • 2011.10.17 07:41 8968 Rajan • Lively Capital • Sheet 82 of 506

PROOF



*The optimal community effectiveness curve shows the number of CHD deaths avoided if the highest risk people were treated first
A=The effectiveness gap or the difference between the potential deaths avoided by the guideline recommendations compared with the optimal number of deaths avoided if the highest risk people were recommended treatment.
B=The efficiency gap or the difference between percentage of the population recommended statin treatment compared with the minimum population that could be treated to avoid the same number of deaths.
NNT=Number needed to treat to prevent 1 CHD death over 5 years

1. Number of deaths from coronary heart disease (CHD) prevented over five years by percentage of Canadian population aged 20–74 years treated with statins for different national guidelines for the management of dyslipidaemia. From Manuel et al. 2006, used by permission.

and of consequent guidelines would be based instead on how far to right they would appear on the graph, which translates into vastly more treatments. Thus Schacter states clearly, "The challenge for the project team is to design the most efficient development plan, within the regulatory and ethical constraints, that will provide the largest market, and the best return on investment. The trials should be no larger, nor run longer, than required to provide evidence for efficacy and safety" (2006, 117).

It comes as no surprise, perhaps, that the U.S. guidelines are the furthest to the right and getting more so with each guideline revision. The medical historian Jeremy Greene notes that once Merck had started conducting clinical trials for its drug Mevacor so that they reinforced the then controversial cholesterol guidelines, subsequent trials by many companies "came to exert a formative influence on the guidelines themselves" (2006, 197). At

Tseng Proof • 2011.10.17 07:41 8968 Rajan • Lively Capital • Sheet 83 of 506

PROOF

the same time, there is nothing inherently wrong with any of these guidelines. The revised U.S. guidelines are projected to save approximately 300 more lives per five years than New Zealand's (15,000 versus 14,700), at the mere cost of putting 12 percent more of the population on statins (24 percent versus 12 percent).

Rose's struggles with this entailment of his preventive-health proposal reflects the inability of the logic of prevention to stop the biomedical appropriation of clinical trials. Almost ironically, Rose notes the "folly" of those health-service managers and policymakers who get so caught up in mistaking "people treated" for improved health that they say things like, "This has been a good year for the National Health Service. . . . [W]e have treated more patients than ever before." Rose's assessment is that they are managing health services "according to the principles of the market" (Rose, Khaw, and Marmot 2008, 38). Precisely! Rose nowhere seems to recognize that what he calls this "blinkered attitude" is the very goal of pharmaceutical marketing.

> Drug companies commonly control the research question (with what products and what doses, and for what patients and conditions, is the new drug compared?), they control the selection of patients for the trials, they control how drop-outs and side-effects are reported and treated in the analysis, and they control what information makes its way into scientific presentations and peer-reviewed publications. Drug companies often use surrogate endpoints to establish a product's efficacy (and to establish a market for the product), despite absence of evidence that the surrogate outcome and health status are in fact correlated, and sometimes, in the face of evidence that they are not. (Morgan, Barer, and Evans 2000, 661)

In this manner, biomarkers undergo a transformation from being additional signs of an illness or risk of one into being the means of defining a new illness for treatment.[19] Symptoms become commodities not because they are paid for, or even because they involve biomarkers, but because that is the only way to decide on illness. The person is dependent on the clinical-trial evidence for knowing whether or not he is ill and needs treatment. And the patient has no way of knowing whether or not a test finds a real thing, or whether the treatment works. The switch to "preventive, population medicine" makes it possible for the biomarker to become the "fact" that defines an illness for treatment, with its attendant consequences.

Rose's argument is cited by pharmaceutical companies in their explanations of what they have been up to! "Defining illness is somewhat arbitrary.

Tseng Proof • 2011.10.17 07:41 8968 Rajan • Lively Capital • Sheet 84 of 506

PROOF

Blood pressure and lipid levels, for example, have a normal 'bell-shaped' or 'n-shaped' distribution. In such cases, the abnormality is quantitative rather than qualitative. As a result, the point at which clinicians decide that something is abnormal and therefore warrants treatment, is an arbitrary decision usually based on population risk (Rose 2008, 6–8). This means that different clinicians can—and sometimes do—draw different conclusions about the point at which they will intervene. Clearly such factors can influence the success of a particular medication" (Greener 2001, 47). It was in fact this citation of Rose in Greener's guide to the pharmaceutical industry that led me to his *Strategies for Prevention* in the first place. Rose's lack of understanding of the political-economic context of clinical-trial operations causes him to overlook the true function of clinical trials in biomedical capitalism in the same way that economists missed the function of machinery in capitalism. It is Rose, then, who wears blinders, for marketing must insist that the clinical trial be designed such that success will generate a bigger and more profitable market in prescriptions, whereas Rose assumes that the point of designing a clinical trial is to maximize healthiness in society and that this requires careful discussion of the tradeoffs between the size of the population indicated by the clinical trial and the costs of treating that population.

All of Rose's assessment modes are moot in the context of pharmaceutical companies, whose criteria of value is number of prescriptions. Those companies are quite explicit in calling for the maximum market size that can be reliably diagnosed. The pharmaceutical management consultant Arthur Cook provides an example in his *Forecasting for the Pharmaceutical Industry*.

> For the patient-based forecaster success-stories revolve around diseases such as benign prostatic hypertrophy and HIV. Benign prostatic hypertrophy (BPH) is a disease that affects men, usually in older age. Cadaveric epidemiological studies suggested that the prevalence of BPH was as high as 95 per cent in men over the age of 65. However, the number of men treated for BPH was significantly lower. With the advent of new diagnostic technologies, physicians were able to monitor for an enzyme associated with BPH and were able to diagnose patients earlier in their disease. This led to market growth through an increase in diagnostic rates. (Cook 2006, 41–42)

Cook here shows how since pharmaceutical companies have begun to operate the clinical trials that define the facts about illnesses and risks, patients are quite literally forced to rely on those facts and to submit their healthiness

Tseng Proof • 2011.10.17 07:41 8968 Rajan • Lively Capital • Sheet 85 of 506

PROOF

to screening and diagnosis. The healing and *actual* risk reduction the patient receives is the equivalent of wages in *Capital*. But what of the excess or surplus? Say the NNT is 50, then for every 50 patients who are diagnosed and treated, 49 are treated without needing that treatment. For BioMarx, their treatments are surplus and the healthiness used (that is spent in screening, purchasing prescriptions, and side-effects) is "surplus health."

But isn't this the public-health argument and the prevention paradox? Yes, and no. What makes the difference in machinery is not in the machinery-worker relation, but in the capital dynamic that makes it the *means* for profit on investment.

> Now in order to allow of these elements actually functioning as Biomedicine, the Pharmaceutical Pharma requires additional Health. If the exploitation of the Patients already Treated do not increase, either extensively or intensively, then additional Healthiness must be found. For this the mechanism of Pharma Medicalization provides beforehand, by converting the Patient Class into a class dependent on Risks, a class whose ordinary Risks suffice, not only for its maintenance, but for its increase. It is only necessary for Biomedicine to incorporate this additional Healthiness, annually supplied by the Patient Class in the shape of Patients of all ages, with the surplus means of Medicalization comprised in the annual Medicalize, and the conversion of surplus-Illness into Biomedicine is complete. From a concrete point of view, accumulation resolves itself into the Return to Healthiness of Biomedicine on a progressively increasing scale. The circle in which simple Return to Healthiness moves, alters its form, and, to use Sismondi's expression, changes into a spiral. (B-C1: ch. 24)

In biomedicine, the current market for a drug is the limited viewpoint, and to reframe it we need to take into account everyone who might *possibly* be able to take the drug. In this worldview, the first step is to not to look at those who already visit their doctors, but to take a potential threshold diagnosis and calculate how many people *would* be part of that threshold and therefore *should* be consumers of the relevant drug. Interviewed in the industry journal *Pharmaceutical Executive*, an Aventis executive, Thierry Soursac, describes this process: "'Up until now,' he says, 'when we were looking at the size of the market, we tended to open this market data bible called IMS and say, Okay, the market of proton pump inhibitors is that much, and the market of hypertension is that much, and this is the size of the market we have to tap into.' The problem, Soursac explains, is that IMS data represent

Tseng Proof • 2011.10.17 07:41 8968 Rajan • Lively Capital • Sheet 86 of 506

PROOF

a 'rearmirror view' of markets, a view of the past, not the potential" (Shalo 2004). Soursac's reference to the problem of the rear-mirror view of markets is almost an exact quote from *Every Business Is a Growth Business*, this time referring to Robert Nordelli, the chief executive officer of General Electric Power Systems. Pharmaceutical executives, in other words, have already been translating capital into biomedicine, substituting health for value and illness for labor.

The question thus arises: how big is the market for statins or other drugs? One approach, used by most drug companies, has been to measure the number of diagnoses for the indication and use this as a benchmark for market size. One company, IMS Health, is the acknowledged leader in this type of information gathering. IMS tracks almost every prescription written by every doctor, then sells this information to marketers and drug companies so they can track exactly how well their campaigns are going. "[Soursac's] entire marketing strategy hinges on his belief that pharma companies need to 'look at how many human beings on the planet have specific diseases that can be addressed by our drugs; this is the market. Whether this market has translated into any sales of drugs in the past is irrelevant.' Soursac cites the possibility that a market with low sales may be suffering from underdiagnosis of a condition or poor documentation of disease epidemiology in certain geographic areas" (Shalo 2004). When Soursac suggests looking at who on the planet "has the disease," he means to estimate the number of people who could be determined to be below a specified threshold. Arguing then from this "potential," he outlines a strategy for achieving it, beginning with changing how the disease is diagnosed and how it is documented.

One way to grow a megamarket is to emphasize underdiagnosis by identifying a hidden epidemic. In one instance of market production in Japan, for example, targeted epidemiological studies were designed specifically to show undetected, even unimaginable levels of deep venous thrombosis (DVT) and thus to literally create a market for its diagnosis and treatment. "'People in the company said there are too few patients in Japan,' [Soursac] says. 'But I looked at the U.S. and Europe. . . . And thought this is sure to be a big market'" (ibid.). This approach is a textbook business-growth tactic, emulating Goizueta's admonition that that Southern California's average monthly Coke consumption could be tripled because Hungary's consumption was three times greater per month. Growth for Goizueta was premised on the notion that ideals, and not averages, were appropriate target norms. So Soursac commissioned a third-party epidemiology study that found rates of disease in Japan to be identical to those in the United States. "'Suddenly,

Tseng Proof • 2011.10.17 07:41 8968 Rajan • Lively Capital • Sheet 87 of 506

PROOF

by having that data in your hand and being able to share it with the health authorities and medical institutions, you certainly create the market for diagnosis and treatment of DVT which didn't exist before'" (ibid.).

National populations and potential markets are made equivalent through epidemiology and international-standards bodies. Factual humanitarian claims of disease prevalence are mobilized to invoke nation-state ethical responses, opening up markets. Health facts, in Soursac's view, are highly contestable. If epidemiological data suggests one conclusion, another study might counter it. The result would seem to be a contradiction or even a controversy. But when the data are properly shared, emphasized, and amplified, a new patient-population-in-waiting can be created whole cloth, where "one didn't exist before."

> Pharma does not know that the normal Prevalence of Health also includes a definite quantity of Unneeded Health, and that this very Unneeded Health is the normal source of his gain. The category of surplus Health-time does not exist at all for him, since it is included in the normal Treatment-Time, which he thinks he has Needed for in the day's Healthiness. (Ch. 20)

Here we can return to the unimaginable and virtually infinite numbers of people at high risk prophesied by Cleeman, and inflect these numbers with the materialization of theory by Soursac. One reason why we cannot imagine how many people are at risk and need treatment is because the population does not exist until the questions are posed.

In this remarkable perspective shift, we see how pharmaceutical marketers and executives envision health: as a growth opportunity and a virtually unlimited one. Could they be right? Could we be headed for a world in which greater numbers of drugs are taken for life, such that it comes to be our bodily intolerance to multiple drugs taken simultaneously, rather than our lived health, which provides some sort of limit? Can the number of drugs that Americans consume continue its double-digit growth for another century?

replace all [hour(s)] with [Treatment(s)]

Intensification: From Mass Patients to Chronic

Health care has changed dramatically in the past 35 years, as treatment has increasingly migrated from the doctor who directed care in the hospital to patients who now prevent illness through medication use in an unsupervised community setting. . . .

Tseng Proof • 2011.10.17 07:41 8968 Rajan • Lively Capital • Sheet 88 of 506

PROOF

> [M]edications [now] treat illnesses early in their natural history, long before painful or disabling symptoms are apparent. . . . With [these] asymptomatic conditions, patients are often unable to determine if they need treatment at all and/or whether the product is working. . . . This difficulty is only likely to grow. As researchers unravel the molecular basis of an illness, *manufacturers increasingly turn incurable diseases into merely chronic ones*.
>
> **WINDHOVER INFORMATION INC., "MOVING BEYOND MARKET SHARE" (EMPHASIS ADDED)**

Thus we see, that Clinical Trials, while augmenting the human material that forms the principal object of Biomedicine's exploiting power, at the same time raises the degree of exploitation.

> If Clinical Trials be the most powerful means for increasing the Knowledge of Health—i.e., for shortening the Treatment-Time required in the Medicalization of a Symptom, it becomes in the hands of Biomedicine the most powerful means, in those industries first invaded by it, for lengthening the Treatment-Time beyond all bounds set by human nature. It creates, on the one hand, new conditions by which Biomedicine is enabled to give Fearful scope to this its constant tendency, and on the other hand, new motives with which to whet Biomedicine's appetite for the Health of others.
>
> **BIOMARX, *BIOMEDICINE***

Soursac's policy of finding the epidemiology to back up projections is an example of efforts to increase the number of people on a treatment as much as possible, but it still runs into limits. Maximizing markets by choosing the most profitable diseases and maximizing the number of people indicated by clinical trials are only the first steps; the next is to maximize the length of time people stay on a treatment by increasing the number of prescriptions per diagnosis. One way to achieve this is to study younger pools of risk patients. Bartfai and Lees explain how biomarkers enable this extension: "Drug companies do not have the time to wait for the actual therapeutic effect to manifest itself. . . . That is why the designers of clinical trials are always looking for 'surrogate endpoints'; that is you look for something which indicates the therapeutic effect indirectly" (2006, 121).

They use the example of chronic slowly progressing diseases like osteoporosis, rheumatoid arthritis, and Alzheimer's.

> If you want to look at the disease progression of say a neurological disease such as alzheimers (AD), the length of the study becomes a major financial and marketing issue. Since the disease can be detected much

Tseng Proof • 2011.10.17 07:41 8968 Rajan • Lively Capital • Sheet 89 of 506

PROOF

> earlier, one can elect to perform the trial on patients with mild to moderate symptoms, as defined neuropsychologically, and try to show efficacy against a slow decline, but that can take 24 to 36 months. The market size will of course be much bigger; they are younger and there are more of these patients who are less likely to die from other causes during the trial. (Bartfai and Lees 2006, 156–57)

In this passage, Bartfai and Lees demonstrate how one can choose to study the mild, earlier forms of a disease, which will vastly increase both the number of people in the market (as well as the NNT) and the length of time each of those people are on the drug. Pharmaceutical companies face enormous pressure to redefine diseases this way, by studying them with the purpose of identifying a market that is as large as possible.

> Hence that remarkable phenomenon in the history of Modern Pharma, that the Clinical Trial sweeps away every moral and natural restriction on the length of the Treatment-Time. Hence, too, the economic paradox, that the most powerful Test for shortening Health-time, becomes the most unfailing means for placing every moment of the Patient's time and that of his family, at the disposal of Pharma for the purpose of expanding the Illness of his Biomedicine. (B-C1:532)

The source of this expansion possibility lies in the fact that treatment value is counted via the total number of prescriptions. This was brought home to me when, in talking with a group of marketers about chronic illness and poring over a large flowchart of patient decision points, I was directed to a loop in one corner of the chart where repeated prescriptions were encapsulated. "We would love to increase the number of prescriptions a patient takes," said the marketer, "because the profit is the same if one patient takes a drug for four months, as it is for four patients taking the drug for one month." This interchangeability of patient numbers and prescription consumption is reflected in the Express Scripts report under the combined of "utilization," which is prevalence (the number of people indicated for the dug) times intensity (the average length of prescription per patient).

The effect of quantitatively extending risk in this way not only places more people in the category of "at risk," but essentially changes the *quality* of the disease, rendering it chronic. This illustrates the fact that, from the marketer's perspective, "the economic driver in health care has shifted from the physician to the patient. While physicians continue to control episodes of short-term, acute illness, such as hospitalizations, patients increasingly

Tseng Proof • 2011.10.17 07:41 8968 Rajan • Lively Capital • Sheet 90 of 506

PROOF

drive the financial and clinical outcomes for chronic diseases through the simple daily act of taking a pill, often over a long period of time. In financial terms, the shift from acute to chronic care medicine means that between 75–80% of a prescription's value is now concentrated in the patient's return to the pharmacy for refills" (Windhover Information Inc. 2002, 64). The point being made here, in a pharmaceutical report published in 2002, is that if one were to compare two clinical trials, one for a cure and one for a chronic treatment approach to a disease, one would find the latter to have a four to five times better chance of becoming a blockbuster.

Similarly, Michael Kremer and Christopher Snyder investigate why drugs are more profitable than vaccines.

> In a simple representative consumer model, vaccines and drug treatments yield the same revenue for a pharmaceutical manufacturer, implying that the firm would have the same incentive to develop either ceteris paribus. We provide more realistic models in which the revenue equivalence breaks down. . . . The second reason for the breakdown of revenue equivalence is that *vaccines are more likely to interfere with the spread of the disease than are drug treatments, thus reducing demand for the product*. By embedding an economic model within a standard dynamic epidemiological model, we show that the steady-state flow of revenue is greater for drug treatments than for vaccines. (Kremer and Snyder 2003, emphasis added)

Kremer and Snyder make explicit that in too much drug research, cures get in the way of repeat revenue. The corollary of seeing clinical trials as instruments or means for maximizing prescriptions especially when used to lengthen treatment time is that everything that gets in the way of those treatments becomes a *loss*. Since the expected return-on-investment for a clinical trial is the total possible prescriptions, everything which impedes their realization is perceived as a barrier to overcome. BioMarx says something very similar after stating that "the development of this objective Healthy Life is in opposition to, and at the cost of, the human individual."

> The productivity of Health in general = the maximum of Risk Diagnosis with the minimum of Health, hence the greatest possible cheapening of Symptoms. This becomes a law in the Biomedical mode of Medicalization, independently of the will of the individual Pharma.

A version of the flowchart the marketers showed me, with patients' return for prescriptions, appears in almost every pharmaceutical textbook.

Tseng Proof • 2011.10.17 07:41 8968 Rajan • Lively Capital • Sheet 91 of 506

PROOF

What I didn't understand at the time is that what the marketers call "utilization" (Express Scripts) is, from the user's point of view, "bioavailability," the overall availability of an individual's metabolism for the maintenance of pharmaceutical flows.[20] The consequence of this formulation is that marketers envision patients literally as points of resistance (rather than of consumption). Their physiological rejection of many drugs, their desire to stop taking different treatments, even their sense of their own wellness are all obstacles to be overcome. "Applying such metrics to a variety of chronic disease states reveals that a marketer's real enemy is less the share lost to competitors than the cumulative effects of patient attrition over time" (Windhover Information Inc. 2002, 69).

Note that this means that marketers are directly opposed to your decision not to continue taking a prescription because you feel better or want to try an alternate form of medicine. The business magazine *Forbes* reinforced this battle image with a cover story on *Pharma's New Enemy: Clean Living*. Recalling Goizueta's redefinition of the Coke market toward human liquid consumption, which he declared as a war on coffee, tea and tapwater, the point here is that for good business reasons, Pharma has found a way to grow through declaring war on living without drugs. Or as BioMarx puts it: "*If the Patient Heals his disposable time for himself, he robs Pharma*" (B-C1: ch. 10).

What seems absurd here, that medical research could define healthiness as its enemy rather than a goal is precisely the absurd paradox that confronted Marx regarding the factory. Extending the analogy in which machinery is equivalent to clinical trials, we see that the logical counterpart to hours is treatments or prescriptions. As investments, factories and machinery come to be seen by capitalists as in need of maximization; any time those machines are not in use comes to be experienced as a loss, no matter how absurd that perception may be. Marx describes this transmogrification of factories into entities that require laborers, which in turn requires laborers to work as long as possible.

> Furnaces and workshops that stand idle by night, and absorb no living labour, are "a mere loss" to the capitalist. Hence, furnaces and workshops constitute lawful claims upon the night labour of the work-people. The simple transformation of money into the material factors of the process of production, into means of production, transforms the latter into a title and a right to the labour and surplus labour of others. An example will show, in conclusion, how this sophistication, peculiar to and characteristic of capitalist production, this complete inversion of the relation be-

Tseng Proof • 2011.10.17 07:41 8968 Rajan • Lively Capital • Sheet 92 of 506

PROOF

> tween dead and living labour, between value and the force that creates value, mirrors itself in the consciousness of capitalists. (C1: Ch11)

Marx goes on to quote a "grotesque" passage in which a mill owner considers his "property damaged" when workers don't work long enough to keep the machines running at all times and thus fail to maximize the capitalist's return on investment.[21] The counterpart in biomedicine is that, from the perspective of pharma, a drug's possible market becomes its *expected* market, and every person for whom that drug could be indicated is seen as a loss of revenue if he or she is not in fact taking the drug.

Mickey Smith's *Pharmaceutical Marketing* includes a chart on the "Decomposition of the Market," which lists the math through which patients with chronic condition X (1,000,000) translates eventually into only 7,350,000 prescriptions whereas there was an "original potential" of 12,000,000 prescriptions (1 million patients × 12 prescriptions). The remainder is termed "Prescriptions 'Lost'" with "Lost" in quotation marks, as if Smith knows he is treading on ethically suspect grounds; but in the summary chart, defined in terms of the potential market, the remainder is simply listed as "Total Prescription Loss." Smith uses this chart to make the point that increasing compliance may be cheaper than increasing market share.

This type of paradox arises, according to Marx, because capitalists do not employ machines *in order to* produce things and generate material wealth for society, but perceive material wealth *merely as a means* to make more money.

> This contradiction comes to light, as soon as by the general employment of machinery in a given industry, the value of the machine-produced commodity regulates the value of all commodities of the same sort; and it is this contradiction, that in its turn, drives the capitalist, without his being conscious of the fact, to excessive lengthening of the working-day, in order that he may compensate the decrease in the relative number of labourers exploited, by an increase not only of the relative, but of the absolute surplus-labour. (C1:531, ch. 15)

For BioMarx, it is no less tragic.

> This contradiction comes to light, as soon as by the general employment of the Clinical Trial in a given Market, the Illness of the Threshold-Medicalized Symptom regulates the Illness of all Symptoms of the same sort; and it is this contradiction, that in its turn, drives Pharma, without his being conscious of the fact, to excessive lengthening of the Treatment-Time, in order that he may compensate the decrease in the relative num-

Tseng Proof • 2011.10.17 07:41 8968 Rajan • Lively Capital • Sheet 93 of 506

PROOF

> ber of Patients exploited, by an increase not only of the relative, but of the absolute Surplus-Health. (B-C1:531)

The phrase "without his being conscious of the fact" is stunning, and intriguing. Marx does constantly attend to the psychology of the capitalist, whom he sees as structurally produced ("this contradiction in turn drives Pharma"). He points out, for instance, that what may appear at first glance to be miserly greed, the impulse to accumulate, must in fact be understood as a kind of possession: Capital possesses the capitalist, such that seeing through Capital's eyes—from Capital's point of view—comes to be so deeply embedded that it blinds the capitalist to all else. Thus, Marx says, Capital inhabits the soul of the capitalist.

It is only the notion of possession by capital that prepares me to understand the following claim, which is otherwise, to me, incomprehensibly callous.

> Looking at the business of mental disease objectively, but without cynicism, a common denominator of these indications is that they share the distinction of not being cured by these pharmacological treatments. This makes the market even more attractive. The patients have to take the drugs chronically. Not only are the diseases not cured, but there are few treatments that give 100% relief to those who have a syndrome. All usual response rates are 60 to 70% for a really good drug. . . . This gives a double opportunity: (1) one can enter a partially saturated market with a drug that works on patients unresponsive to existing treatments; and (2) one can improve on the side effect profile or the efficacy in terms of the time required for the onset. (Bartfai and Lees 2006, 221)

"Objectively, but without cynicism": it is as if the authors dimly recognize how outrageous the rest of the paragraph will seem, yet they cannot stop, because the point they are making *is* objective. The world they live in, that we live in, is a world in which medical research *is* a financial investment demanding returns. In our world, it is objectively true that drugs that cure people or stop the spread of a disease (like vaccines are supposed to do) "reduce revenue." Chronic treatments are more valuable to research, and drugs that work only on a subset of people (i.e., those with a large NNT) generate more prescriptions (by indicating a larger market) than those that treat everyone they are indicated for (i.e., those with an NNT of 1). This is the reality of biomedical capitalism within which we and the pharmaceutical companies must operate and survive.

Tseng Proof • 2011.10.17 07:41 8968 Rajan • Lively Capital • Sheet 94 of 506

PROOF

Bartfai and Lees claim their view is "without cynicism." That is, while it might appear as if they are speaking in a scornful and bitterly mocking attitude, as if they were motivated only by selfish interests, they are not. What they are saying, in essence, then, is that unlike Marx's capitalists they are *consciously* possessed and understand clearly that they have no choice but to "excessively lengthen treatment time . . . beyond all bounds set by human nature," to let BioMarx rephrase them. "Cynicism" would imply that they had based their analysis on selfish motives and that they therefore believe it to be the product of human nature. But they rest in the knowledge, instead, that their conclusions simply reflect the objective contradictions of healthcare.

> What is a Treatment-Time? What is the length of time during which Biomedicine may Heal the Illness whose daily Diagnosis it buys? . . . [I]n its blind unrestrainable passion, its were-wolf hunger for surplus-Health, Biomedicine oversteps not only the moral, but even the merely physical maximum bounds of the Treatment-Time. . . . It reduces the sound sleep needed for the restoration, reparation, refreshment of the bodily powers to just so many Treatments of torpor as the revival of an organism, absolutely exhausted, renders essential. It is not the normal maintenance of the Illness which is to determine the limits of the Treatment-Time; it is the greatest possible daily expenditure of Illness, no matter how diseased, compulsory, and painful it may be, which is to determine the limits of the Patients' period of repose. Biomedicine cares nothing for the length of life of Illness. All that concerns it is simply and solely the maximum of Illness, that can be rendered fluent in a Treatment-Time. (B-C1: ch. 10)

A different sort of logic was proposed by two researchers in the *British Medical Journal* in 2004. Based on a meta-analysis of existing risk, biomarker, and threshold trial data, the authors proposed a single multipill that would save lives to such an extent, they argued, that everyone over fifty-five should be mandated to take it. Their logic is an extension of Rose's prevention analysis. In a nod to cost, but not to consent, they suggest that a low-cost version of this polypill, using generic components off patent, would work, even if "10% of the users were intolerant" (Wald and Law 2003, 4). "Intolerance" here is a formulation of the literal limit of the body's resistance to too many drugs, that is, when it throws them up. Their proposal thus involves calibrating the drug to the maximum number of effects, side effects, and cost that society will tolerate before rebelling (the NNT of the polypill was estimated to be between 600 and 800).

Tseng Proof • 2011.10.17 07:41 8968 Rajan • Lively Capital • Sheet 95 of 506

PROOF

With "bodily intolerance" we confront the same ultimate physiological barrier that Marx's capitalists found with labor, and that Goizueta found with Coke: the surprisingly expandable but not unlimited elasticity of the human body. Where Goizueta suggested that the target for Coke's growth was human liquid-consumption capacity, Marx locates it in the labor humans can be pushed to do, and BioMarx in the body's tolerance for pills.

> And this law is only realized because it implies another one, namely that the scale of Medicalization is not determined according to given needs, but rather the reverse: the number of Risk Diagnoses is determined by the constantly increasing scale of Medicalization, which is as much Undiagnosed health as possible, and this is only attained by engaging in Medicalization for Medicalization's sake. (B-PEM 1038)[22]

Their article concludes with a call for the end of thresholds altogether by taking them to their natural limit: "It is time to discard the view that risk factors need to be measured . . . everyone is at risk" (Law and Wald 2003, 4). This is a naturalized form of the suggestion to "put statins in the water supply," no longer even a half-joke, but a policy proposal.

Conclusion
replace all [laborer(s)] with [Patient(s)]
replace all [wage] with [Risk]
replace all [wage-laborer(s)] with [Patient(s)-at-Risk]

We see then, that, apart from extremely elastic bounds, the nature of the Measure of Symptoms itself imposes no limit to the Treatment-Time, no limit to surplus-Health. Pharma maintains his rights as a purchaser when he tries to make the Treatment-Time as long as possible, and to make, whenever possible, two Treatment-Times out of one. On the other hand, the peculiar nature of the Symptom Submitted implies a limit to its Healing by the purchaser, and the Patient maintains his right as Submitter when he wishes to reduce the Treatment-Time to one of definite normal duration. There is here, therefore, an antinomy, right against right, both equally bearing the seal of the law of Measures. Between equal rights force decides. Hence is it that in the history of Pharma Experience, the determination of what is a Treatment-Time, presents itself as the result of a struggle, a struggle between collective Biomedicine, i.e., the class of Pharma Companies, and collective Health, i.e., the Patient Class.

BIOMARX, ***BIOMEDICINE***

Tseng Proof • 2011.10.17 07:41 8968 Rajan • Lively Capital • Sheet 96 of 506

PROOF

In using Marx to construct BioMarx, I did not assume that he was correct about the economy. Rather I attended carefully to the careful way in which he read the capitalists and the economists of his day. He attempted to make explicit the logic of their way of valuing the world, which was via labor. He found this directly in their writings: in the way they kept their account books, the way they complained about wasted labor, and the way they chose to invest in machinery (or not). In this manner he executed a close reading of their practices as they were enabled by their perspective—the materialization of their theories of value. By following the logic of the competing demands of this perspective—the way in which growth, for instance, becomes critical for a company's survival—he tried to show that apparently contradictory results, like constant crises, were results of this logic. And in turn he was able to show how the actions of capitalists made sense in light of this logic.

I, too, have had to adopt this convoluted approach, as I have been confronted with apparently absurd and sometimes vile practices by pharmaceutical companies, and with corporate statements that have, in a calm, objective, and at times defensively complaining voice, logically justified those practices. I did not attend to the scandalous practices of cheating in a clinical trial, suppressing research, or ghostwriting results, but rather to the need to develop drugs for diseases that affect the insured middle class and to avoid focusing on diseases that largely affect the poor, and to the need to define illness as risk and increase as much as possible the number of treatments, even if this means that most of the people being treated would not benefit from the drug.

When I've assessed these latter practices without the context and logic unearthed by BioMarx, it has been impossible to understand pharmaceutical companies as anything but predatory. Using Marx in this way helps clarify the logic that drives pharmaceutical companies as a logic that is not exclusive to that particular corporate culture, but is shared by all of us—and that it is a historically specific logic, a way of seeing health qua mass health as risk reduction, that results in health being defined via treatments.

When I presented a talk on this material (without mentioning Marx) as grand rounds to the psychiatry department at Alta Bates Medical Center, the first question I got was "Is there any hope?" The second was "What do you recommend we do?" BioMarx suggests we are only at the beginning of a transformation of health. In analogy to the fight over the length of the working day, BioMarx suggests that there will be increasing struggles over how much medicine we can be mandated to take. Perhaps the various debates

Tseng Proof • 2011.10.17 07:41 8968 Rajan • Lively Capital • Sheet 97 of 506

PROOF

regarding the new "vaccines"—like a herpes papilloma virus vaccine for all girls ages nine to thirteen, and a meningitis vaccine for all children—are signs of this. And will the same happen with the polypill? Will there be a fight to determine the level of drug intake we are forced to tolerate?

> One of the most important problems, therefore, which the Diagnoser of a Health Market has to solve is to find out the maximum speed at which he can run, with a due regard to the above conditions. It frequently happens that he finds he has gone too fast, that breakages and bad Treatment more than counterbalance the increased speed, and that he is obliged to slacken his pace. (B-C1: ch. 10)

Reading BioMarx this way, I have started having little out-of-body experiences. The future is calling me. This nightmare future where, when we wake up, we first check the latest clinical trials, then order our pack of pills for the day. Some people—the "intolerants" we call them—have negative reactions to the pills. This is not their fault, as they protest, but their insurance goes up all the same.

In this future, there are still two parties: the More-Lifers rule on a platform of immortality. Life extension is a reality, they say, as long as we all do our part and participate in enough clinical trials. The opposition party—More-Choicers—complain that health is not a formula, that we should not be forced to take so many drugs with so many unknown interactions. Current guidelines require monitoring of seventy-five biomarker measures like cholesterol levels (six types), the body-mass index, a composite behavioral-emotional score, and a steady-attention test. In order to receive health coverage, all of these must remain above the acceptable level or one must be taking the appropriate preventative pharmaceutical therapy. There is growing unrest over the legal intolerance rate of 10 percent, meaning that 10 percent of the population has detrimental reactions to the required medications. If the rate isn't lowered below 3 percent, many predict that the More-Choice party may take back the house.

That is my objective paranoid self speaking. My analytic self and the pharmaceutical analysts begin with the tragedy. The more "health" we gain, the more medicine we consume. Key to this is the fact that most clinical trials are designed by the pharmaceutical industry, and in the most mundane capitalist way, this means that they are designed such that if they are successful, they will increase the market in drugs. The corollary is startling: almost all of the facts that we have gathered about our mass health over the last twenty years tell us to take more drugs. They are not bad facts, but they are limited.

Tseng Proof • 2011.10.17 07:41 8968 Rajan • Lively Capital • Sheet 98 of 506

PROOF

We are not asking—and tragically, in our current system, we cannot afford to ask—what sort of "health" we might have if we took fewer drugs. Those facts have not been produced. Until we rethink the infrastructure for the design of large-scale clinical trials and screening tests, this trend will continue—even if we clean up the abuses of clinical trials.

The disturbing analytic problem is that the pharmaceutical executives and marketers seem to be shouting the same thing. Don't blame us, they say. We know the problems better than you do, but we are trapped within them, too, even as we perpetuate them. Thus Mickey Smith explains, "Society has medicalized human problems, it appears. Medicine has perhaps been an accessory, and the pharmaceutical industry, certainly, has provided both with the means. To expect either of the latter parties to do, or have done, otherwise bespeaks a considerable naïvete" (2002, 35).

Similarly, Bartfai and Lees blame two groups "as the real root causes of all the problems the industry and society face" (2006, xvii), including why there are not enough drugs for the people who need them. The groups are "the lawyers who litigate and the venture capitalists who may want too much return from too short an investment and can switch their investments and allegiances on a whim" (ibid. xvii). To point to lawyers distracts from the real insight: the structure of drug companies is that of a capital company whose chief allegiance is to shareholder returns.[23] Whether by venture capitalists or mutual funds, drug companies must always increase returns, and that means more treatments.

Thus it seems we are in a bind, even as we have an ever-increasing number of treatments available, which continually reduces our risk. We call for more regulation, better surveillance of drug companies, and even structure incentives better, like orphan drug laws and granting companies six additional months of patent protection if they study the effects of their drugs on children. We get more information on relative safety, companies get more money, and, predictably, children end up taking more and more drugs (reducing their risks more).

But this use of *we* marks me as a medically insured U.S. citizen most deeply. My suspicious ears hear another trend being traced by the ethnographies of clinical trials conducted globally. There is a much bigger, global story to tell about clinical trials that is the object of ongoing research by Kaushik Sunder Rajan, Adriana Petryna, Kris Peterson, myself, and others.

The insidiously banal logic of modern-day pharmaceutical industry growth drives clinical trials in ways that have become so naturalized that it is hard to imagine health research in any other way. How is it that we live

Tseng Proof • 2011.10.17 07:41 8968 Rajan • Lively Capital • Sheet 99 of 506

PROOF

with, love, and ingest medicines produced through this same experimental zone? How is it that our privileged consciousness sees this as all so natural, our bodies willingly given over, and other bodies so easily made invisible?

replace all [materials] with [Bodies]
replace all [property] with [Life]
replace all [price] with [Prevalence]
replace all [profit] with [Market-Increase]

Notes

1. IMS Institute for Healthcare Informatics, *The Use of Medicines in the United States: Review of 2010* (Parsippany, N.J.: IMS Health Incorporated, 2011); Office of the Actuary, Centers for Medicare and Medicaid Services, *National Health Expenditures, Forecast Summary and Selected Tables*.

2. This scale allows for tremendous variation. Huge disparities exist in prescription rates by state, and by counties in states, and within counties. Often a single prescriber can increase the prescription consumption in an area five- to tenfold.

3. Formulation from Sunder Rajan 2006.

4. The old guidelines held that blood levels of low-density lipid (LDL) cholesterol, the bad kind that clogs arteries, should stay below 100 milligrams per deciliter (mg/dL) and, ideally, below 70 mg/dL for very high-risk patients. According to the new advisory, issued in 2006, those guidelines are now recommended for all people with established heart disease. See Edelson 2006.

5. See https://sites.google.com/site/biomarxexperiment/home. The original is at http://www.marxists.org/archive/marx/works/1867-c1/index-l.htm.

6. See appendix A for a list of the substitutions. I have not thought through even in passing the relations of biocapital in the sense that Kaushik Sunder Rajan (2006) uses it; the capitalization of biology in the sense used by Hannah Landecker (2007); the commodification of bodies in either Adriana Petryna's take on health or clinical-trial trafficking (2005) or in Lawrence Cohen's take on organs (1999); or the proposed rewriting of *Capital*, vol. 3, by Sarah Franklin and Margaret Lock (2003).

7. Other words may be more appropriate for other areas of analysis. If anyone has terms they would like to experiment with, I can easily code them and produce a substituted *Capital* in less than a minute. Automation does save labor!

8. All quotes from *Biomedicine* I have left in the raw automatic-substitution format. Please see the websites for the full text of *Biomedicine*.

9. The inspiration for this origin story lies in the work of the Socialist Patients Kollectiv (SPK) (Sozialistisches Patientenkollektiv 1993).

10. See Greene 2006 on the history of this since the 1960s.

11. "Are You the Picture of Health?" campaign for colorectal-cancer screening. Available at the Centers for Disease Control and Prevention website, http://www.cdc.gov.

Tseng Proof • 2011.10.17 07:41 8968 Rajan • Lively Capital • Sheet 100 of 506

PROOF

12. [Fixed Biomedicine and the Development of the Knowable Forces of Society] NOTEBOOK VII, End of February, March. End of May–Beginning of June 1858, The Chapter on Biomedicine (continuation).

13. Compare Petryna 2005, Sunder Rajan 2007, Fisher 2009, Petryna, Lakoff, and Kleinman 2006, and Peterson, chapter 7 in this volume.

14. See for instance J. Urquhart, "Some Key Points Mmerging from the COX-2 Controversy." *Pharmacoepidemiology and Drug Safety* 14, no. 3 (2005).

15. The work of Moishe Postone, in *Time, Labor and Social Domination* (1993), was extremely useful in helping me to understand this dynamic.

16. Pastoral care or biopolitics in terms of care of the population, from this perspective, is only meaningful when such "care" involves an expanding and constant domain of prophylaxis. Normalization in a Foucaultian sense is meaningless in this regard—the only state of "normality" that generates value is one that expresses an aggregate potentiality of future illness.

17. They continue: "A more profound 'revelation' [than the fact that drug companies deceive us] is that members especially of the U.S. society are prepared to take too many drugs with little provocation" (Bartfai and Lees 2006, xv). This statement speaks fundamentally to why citizens should in no way expect drug companies or any other company to look out for the public interest or even to tell the truth. As Althusser (2006) suggests, the bourgoisie lies easily because the lies are naturalized, continuous, "common-sense" discourses all by themselves.

18. Ironically, cholesterol-lowering drug trials are actually quite numerous because the market is so large that almost every company competes for it (Greene 2006).

19. See Linda Hogle (2001) and Jennifer Fosket (2002) on clinical-trial entry criteria determining "high risk" as a result.

20. See Cohen on bioavailability (Cohen 1999, 2004), as well as the federal definition: "the rate and extent to which the active ingredient or therapeutic ingredient becomes available at the site of drug action" (section 505[j] of the Food, Drug, and Cosmetic Act as amended by Title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 [505(j)(8)(A)(ii)]).

21. During the revolt of the English factory lords between 1848 and 1850, "the head of one of the oldest and most respectable houses in the West of Scotland, Messrs. Carlile Sons & Co., of the linen and cotton thread factory at Paisley, a company which has now existed for about a century, which was in operation in 1752, and four generations of the same family have conducted it," this "very intelligent gentleman" wrote a letter in the *Glasgow Daily Mail*, on 25 April 1849, with the title "The Relay System," in which among other things the following grotesquely naïve passage occurs: "Let us now . . . see what evils will attend the limiting to 10 hours the working of the factory. . . . They amount to the most serious damage to the millowner's prospects and property. If he (i.e., his "hands") worked 12 hours before, and is limited to 10, then every 12 machines or spindles in his establishment shrink to 10, and should the works be disposed of, they will be valued only as 10, so that a sixth part would thus be deducted from the value of every factory in the country."

Tseng Proof • 2011.10.17 07:41 8968 Rajan • Lively Capital • Sheet 101 of 506

PROOF

22. From author's "BioMarx" substitution of the *Economic Works of Karl Marx 1861–1864* at chapter 6: http://www.marxists.org/archive/marx/works/1864/economic/ch02a.htm (at [450]).

23. Lawyers are problematic in that their litigation puts drug companies on the defensive (Smith, Kolassa, Perkins, and Siecker 2002).

Tseng Proof • 2011.10.17 07:41 8968 Rajan • Lively Capital • Sheet 102 of 506