

Coming Soon to a Physician Near You: Medical Neoliberalism and Pharmaceutical Clinical Trials

Jill A. Fisher, PhD

A woman and her son wait for the doctor to see them. The doctor, however, is no longer a clinician. Instead, the white male neurologist has transitioned from treating patients to conducting clinical trials for the pharmaceutical industry. Running studies in diverse therapeutic areas, including Alzheimer's disease, arthritis, diabetes, gastrointestinal disorders, and psychiatric illnesses, this doctor recruits and enrolls human subjects in drug studies through mass media advertisements. This physician is not alone in conducting pharmaceutical research in a research center converted from a private practice; pharmaceutical companies are increasingly contracting with private-sector physicians to conduct their studies. Clinical research responds to US federal regulations mandating that pharmaceutical products be tested on human subjects to ensure safety and effectiveness before they are made available on the market. This physician, like many others, has success-

fully established a company to profit from the regulations.

On this particular day in December 2003, I am shadowing the doctor as part of an extended interview regarding his involvement with pharmaceutical clinical trials. He has invited me to observe his interactions with human subjects and their families so that I will have a better sense of his role. One of these interactions is with the woman and her son. The human subject in this case is the son, a ten-year-old boy who is enrolled in a pediatric study to test the efficacy of a treatment for attention deficit hyperactivity disorder (ADHD). Because the purpose of this visit is to assess how well the investigational treatment is working to alleviate the symptoms of ADHD, the doctor asks a series of questions that are primarily directed to the mother. She explains that from her perspective her son seems to be noticeably more mellow, but that she has concerns about the drug because the boy's teacher is

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Jill A. Fisher, PhD, is Assistant Professor of Women & Gender Studies at Arizona State University. She researches the organization of pharmaceutical clinical trials, especially studies conducted in private practices and for-profit research settings in the US. Her book on the topic (Medical Research for Hire) will be published in Spring 2008 by Rutgers University Press. For more information: www.jillfisher.net

still complaining about his disruptive behavior in the classroom.

While the teacher's impressions of the boy's behavior could be construed as anecdotal or incidental to the clinical trial, they are of primary concern to the woman. This working-class family has no health insurance, so standard medical care is not an option for the woman to address her son's disruptive behavior in the classroom. Under pressure from her son's teacher, the woman has turned to a clinical trial as a means both to provide some sort of treatment for her son and to prove to the teacher her own commitment to addressing the problem.

The situation of neither the physician nor the woman and her son is unique. In the past two decades, the pharmaceutical industry has reorganized the clinical testing of its products. Currently, about 75% of studies in the US are conducted in the private sector by non-academic physicians who recruit their own patients or local community members into the drug studies.¹ Over 60,000 of these studies take place in the US each year, accounting for 75% of the 80,000 clinical trials conducted worldwide,² at a recorded cost of \$34 billion in 2003.³ To execute these studies, more than 50,000 US physicians registered with the Food and Drug Administration (FDA) as principal investigators on one or more clinical trials in 2001.⁴ As for the human subjects, 3.62 million Americans participated in clinical trials in 2003 alone.⁵

Clinical Trials as Health Care "Solutions"

The expansion of pharmaceutical clinical trials in the private sector can be seen

as addressing two problems in American health care: decreasing revenue for physicians and decreasing access to health care for patients. Physicians report diminishing income due to restrictive relationships with insurers and government agencies, ever increasing malpractice insurance premiums and inflated overhead costs to operate private practices. As a result, many physicians are attracted to pharmaceutical contract research because it is perceived as a lucrative field. These physicians are hired as investigators to conduct predefined study protocols that have been developed by scientists and project managers at pharmaceutical companies. As contract investigators, they have no input on study design, inclusion-exclusion criteria dictating which human subjects can enroll in the study, or interpretation of the study results. The participation of these physicians instead involves following the instructions of the pharmaceutical companies in administering the investigational product, collecting the required data, and monitoring the safety of human subjects. More importantly, participating physicians have the right combination of financial motivations and access to patients to make contract research an excellent arrangement for themselves and for the pharmaceutical industry. Thus, clinical research can no longer be said to be the domain of elite academic physicians, but rather an activity in which many private practice physicians routinely engage.

Pharmaceutical clinical trials also serve to fill the health care gap in the US by providing limited medical access to individuals who have no or inadequate health insurance. Clinical trials are frequently marketed to the general public as a way to obtain "free" doctors' visits, diagnos-

tic tests, and medications. Not only do clinical trials promise access to the medical establishment, they also commonly offer stipends to encourage human subjects' participation. On one hand, pharmaceutical clinical trials can be seen as a service for individuals who have health problems but no other means of getting treatment or for individuals who desire to supplement their incomes. On the other, pharmaceutical clinical trials can be seen as exacerbating and profiting from existing social and economic inequalities. The US, with its growing number of uninsured citizens and individuals and families living in poverty, provides fertile ground for recruitment of subjects into drug studies. Although clinical trials provide them with temporary access to medical treatments that they might need, these groups disproportionately bear the burden of risk associated with clinical testing of investigational products and are the most unlikely to benefit long-term from advances in pharmaceutical medicine.

The high prevalence of uninsured Americans in clinical trials is a trend of which most individuals working in the pharmaceutical and clinical trials industries are well aware. Outside of these industries, it is a phenomenon rarely discussed. For instance, there are very few scholarly or popular press publications that focus on the ethics of enrolling the uninsured in clinical trials.^{6,7} The lack of attention to the extent of uninsured Americans' contributions to clinical research may have two causes. First, no federal agency currently requires that data be collected about the insurance status of subjects participating in clinical trials. One research team, however, that collected data on the insurance status of their participants found that uninsured

individuals were seven times more likely than those with insurance to enroll in their heart studies. Other research teams have strategically recruited uninsured populations to fill studies.⁸ For example, a group of researchers found that through the process of direct solicitation, 96% of recruited Latino immigrants – a segment of the US population that tends to have the least access to health care – agreed to participate in their cancer control studies.⁹

A second factor contributing to low levels of awareness regarding the participation of uninsured Americans in clinical trials could be that they participate in clinical trials other than those that usually attract the most public attention. The bulk of popular press coverage of medical research focuses on cancer or HIV/AIDS clinical trials. Cancer studies, in particular, attract a different demographic of participants than do clinical trials for other illnesses that are not fatal or those that already have treatments available on the market. In fact, some evidence suggests that because cancer studies are likely to share costs with insurance companies, Americans without insurance may actually be excluded from participating in those clinical trials.¹⁰ If more public attention turned to clinical trials for chronic – yet, by and large, treatable – conditions such as insomnia, depression, allergies, and weight loss, a different portrait of human subjects would emerge. In other words, what is invisible to most Americans is that the clinical testing of prescription drugs is conducted on uninsured individuals who then lose access to those treatments when they are made available on the market.

Discussions concerning the ethics of clinical trials should be grounded within the twenty-first century context by focus-

ing on the pharmaceutical industry and the participation of private-sector physicians and members of local communities in human subjects research. In order to be relevant to policymakers as they grapple with finding ways to better protect research participants, approaches to the regulation of human subjects research must attend to the social and economic inequalities embedded in the research enterprise and the broader political economy. Specifically, more attention must be given to one important – and often overlooked – characteristic of the political economy in the US: the trend toward the neoliberalization of health care.

Medical Neoliberalism

The term neoliberalism has been used to describe the mode of late twentieth and early twenty-first century governance emphasizing free markets and free trade. Neoliberalism refers to a variation on liberalism as a political philosophy, not popular uses of the term “Liberal” in the US. In fact, neoliberalism is generally associated with the political and economic agendas of conservatives labeled as “Neo-cons.” Although the focus of neoliberal economic policies tends to be international in scope (advocating for globalization and international divisions of labor), neoliberalism affects domestic policies just as dramatically. Neoliberal policies on the national level are manifested in state cutbacks in social goods through the privatization of those functions and the ongoing deregulation of the private sector. An interesting aspect of neoliberalism is that as the state transfers responsibility to its citizens to provide for themselves, it simultaneously increases the

amount of monitoring of citizens’ actions.

Within the US, evidence of neoliberalism can be found in policies surrounding welfare¹¹ and the welfare state’s surveillance of the poor,^{12,13} education¹⁴ and social security.¹⁵ Regardless of the domain of public life, however, neoliberal governance has been the recipient of political spin so that these policies are being framed as in the best interest of the citizenry.¹⁶ For example, the rhetoric of neoliberalism extols the simultaneous benefits that will come to the recipients and the providers of privatized services, stressing the increased efficiency for beneficiaries and the profitability of these systems for private companies. The resulting cultural logic of neoliberalism is articulated in a variety of ways with the same message at its core: what is good for industry must be good for America. What counts as “America,” however, is rarely unpacked. This rhetoric obscures the social burdens placed on American citizens and others by focusing on an economy over which average citizens can make few or no claims. In other words, neoliberalism must be examined on the level of the state and its policymaking but also on the level of its differential effects on citizens depending on their social locations.

Neoliberalism extends into and has particular effects on health care in the US. To understand how the clinical testing of pharmaceutical products fits into this ideology and mode of governance, attention must be given to medical neoliberalism^{17,18} not only as part of broader national trends toward privatized social services, but also as a cultural sensibility toward the commodification of health and wellness.¹⁹ Neoliberalism extends the commodification of health in new ways; under its governing logic, consumption is not only a

right but also an obligation if one wants health care at all.

Within this expanded frame, medical neoliberalism consists of several striking features. First, on the policy level, neoliberal ideologies infuse interpretations of the limitations of the current health care system in the US. Rather than the problem being defined as the system itself, it is instead understood in terms of opportunities for choice. True to its roots in economic liberalism, American health care is defined individually, according to who is willing to pay and for what kind of care. The focus on individual choice, however, serves to obscure the ways in which health care inequalities are generated by the system itself. In other words, medical neoliberalism leads to a prioritization of choice over equity and access.

Second, on the institutional level, medical neoliberalism is characterized by a commodification of health that transforms individuals from patients to consumers.²⁰ The difference in terms is not merely semantic. This new orientation towards medicine not only emphasizes autonomy but also accountability for both patients and health care providers. Unlike patients, consumers seeking health care bear the responsibility for the choices they make – or fail to make – regarding their health. Because they are positioned as having the right to make choices about health care, consumers also have the obligation to utilize whatever products and services are available to ensure health or to treat illness and disease. This is not to say that medical professionals are not liable for malpractice claims. If anything, assessing the appropriateness of care is another burden on consumers, and malpractice suits serve as a means to make claims that the products

and services they sought were not delivered as promised.

Finally, on the cultural level, through the process of making health care a commodity, medical neoliberalism also commodifies the body itself. Medical neoliberalism fragments the body by homing in on specific problem areas with or within the body to the detriment of holistic analysis.²¹ The implication of this fragmentation is that body parts are seen in terms of the products designed to maintain, cure, or enhance them. Potential dangers of this consumerist mode of fragmentation are new perceptions of disability and the rise of “technoluxe”²² and transhumanist²³ models of medicine in which the focus is no longer on health per se but on enhancement of the body.²⁴

In practice, medical neoliberalism is most easily identified in two changes in health care since the 1970s: managed care and direct-to-consumer advertising. President Reagan in the US, along with Margaret Thatcher in the UK, significantly advanced neoliberalism in the 1980s by crafting federal policy in accordance with these political and economic ideologies. For example, in response to the rising cost of medicine and the interpretation of the federal Medicare system as being on the verge of crisis, Reagan ushered in the economically rational strategy of managed care to reduce government spending on health care. After its implementation, the Medicare model quickly became the dominant form of health insurance in the private sector as well.²⁵ This widespread move to reduce the costs of health care in the US was crafted as economic policy. Nonetheless, the changing structure of payment for medical services had profound effects on the culture of medicine. For example, it

can be said to have undermined the authority of physicians, who under managed care must adhere to the rules of medical diagnostics and treatments set by insurance providers.²⁶ In addition, as a response to managed care dipping into their incomes, physicians began to invest in for-profit ancillary-care ventures to spread the reach of the products and services they could offer to patients.²⁷ Ultimately, managed care played a key role in the commodification of health care. By assigning values and standards to clinical practice, medicine became less a social good and more a set of commodities to which individual patients have differential degrees of access.

In addition to managed care, another key example of US federal policy contributing to medical neoliberalism was the re-interpretation of US regulation governing the pharmaceutical industry's right to advertise its products to prospective patients. In 1997, the Food and Drug Administration (FDA) ruled that pharmaceutical companies could market their products to patients themselves through what became known as "direct-to-consumer" advertising. In large part, discourses about patient empowerment and the creation of informed consumers persuaded the FDA to allow mass media marketing campaigns.²⁸

Importantly, the influences of the media and direct-to-consumer advertising have also imposed new constraints on the doctor-patient relationship. These changes in the politics, economics, and cultures of health care in the US have succeeded in re-centralizing power toward pharmaceutical companies and insurance providers and away from physicians. By creating new structures within which medical decision-making occurs, physicians' authority is shared or at times overshadowed by

these industries. For example, due to these third-party influences, patients' perceptions of their health are shaped by targeted messages from the manufacturers of health care products.^{29,30} Nowhere is the extent of neoliberalized medicine more apparent than in current models of treatment for psychiatric illness. In this realm, depression, anxiety, and other disorders are decreasingly located in the contextual lives of individuals with these conditions. Instead, these illnesses are frequently said to inhabit the brain and can thus be treated solely by changing the brain's chemistry rather than finding any psychosocial roots of those conditions.^{31,32}

Patients as consumers have embraced the neoliberal logics of health care so that they too see illness in reductionist terms and seek pharmaceuticals as targeted magic bullets. This orientation toward health and medicine has been referred to as the pharmaceuticalization of health care,^{33,34} in which the conditions of health and illness are ever more cast in terms of products that can be purchased by health-engaged consumers.³⁵ A medical system that revolves around pharmaceuticals contributes to a culture of medical neoliberalism. It ties together the commodification of health care with the fragmentation of the body where illness is treated in terms of discrete systems for which there are tailored products.

Neoliberalism and Clinical Trials

Within political, economic, and cultural contexts of neoliberalism, the offering of pharmaceutical clinical trials is positioned

as adding another option for health care consumers. Because the majority of these pharmaceutical studies are located in familiar contexts, such as private practices in the private sector, the process of research is normalized, meaning that clinical trials become a routine part of the clinic.³⁶ Equally important, neoliberalism in drug testing further fragments the body by positioning illness as a vehicle for testing pharmaceutical products. Under medical neoliberalism, clinical research becomes the “responsible choice” for individuals who do not otherwise have access to – but require – medical intervention. Or, put another way, participation in clinical trials becomes almost a duty for those who have no other access to health care because it is available as a “choice.”

By privileging the individual and choice, a health care system mediated by neoliberal policies and cultural sensibilities tends to obscure the inequalities to which those who participate in clinical trials tend to be subject. Within this frame, the systematic use of the uninsured or economically disenfranchised people as human subjects in pharmaceutical clinical development is not seen as being exploitative, but is instead positioned as an opportunity for members of those groups.³⁷ This discursive maneuver diminishes both the individual risks of participating in drug studies and the broader inequities of the health care and economic systems in the US. Clinical trials may indeed function to address two major shortcomings in American health care – decreasing amounts of revenue for physicians and decreasing access to medicine for patients – but they also exacerbate existing social inequalities and generate new ethical challenges for human subjects research.

The current system of research ethics that is institutionalized through US federal regulation requiring review of study protocols and informed consent of human subjects is disconnected from the political and economic context of clinical trials that I describe in this paper. Current discussions within bioethics and by policymakers tend to focus on the moment of participation both for potential human subjects as well as physicians and others involved in the research enterprise – rather than the conditions that make pharmaceutical studies appealing to individuals and groups. For example, the process of informed consent operates to prevent deception of subjects by researchers and to provide information that subjects can use in decision-making. Yet, most empirical research on informed consent indicates that human subjects decide to participate before reading informed consent forms and that those forms have little impact on subjects’ participation.^{38,39} Likewise, discussions about physicians’ ethics primarily concentrate on the effects of financial conflicts of interests on physicians’ clinical decision-making or judgment about human subjects’ appropriateness for research studies. Yet, these debates around conflicts of interest ignore the fact that financial incentives draw physicians to clinical trials in the first place.⁴⁰ Thus, the approach of examining the ethics of clinical trials at the moment of study participation does not attend to the problems and conditions that make clinical trials an attractive option for certain individuals and groups.

What would it mean for bioethics and policymakers in the US to take the political and economic contexts of pharmaceutical clinical trials seriously? Policies regarding the government’s responsibility to its


citizens in the provision and distribution of health care may at first blush seem incidental to the protection of human subjects, but these policies establish incentives or disincentives to participate in clinical research. By recognizing the ways in which neoliberal policies have created differential access to health care and exacerbated inequality in contemporary society, new questions about the ethics of human subjects research emerge: Is it ethical to rely on uninsured populations as test subjects for the development of new pharmaceutical products? What is required to make the inclusion of uninsured individuals in clinical trials as ethical as possible? How can we ensure that the distribution of risks and benefits of pharmaceutical research is more fair given the problems of access to new products that are experienced by the uninsured? Oftentimes, bioethicists are concerned about reducing coercion that may be felt by prospective human subjects, but there is also a danger in exploiting individuals if they are not sufficiently rewarded for their investment of time and exposure to risk.

For example, the woman and son introduced at the beginning of this paper illustrate the complexity of the ethics of including uninsured individuals in clinical trials. The opportunity that pharmaceutical studies provide for the boy and many others should not be disregarded. The woman is able to leverage this particular study to help minimize her son's problems in the classroom. Yet, what must not be forgotten is that clinical trial participation is not equivalent to medical care. The extent to which the physician running the study can provide medical intervention is constrained by the study protocol. The investigational product, its dose, and

even the administration of a placebo are not chosen by the physician for a patient but by the pharmaceutical company for the provision of study results. Moreover, clinical trials are finite. The woman will have to find another ADHD clinical trial in which to enroll the boy or likely forgo any treatment for him at the conclusion of the current study. If and when the product he is taking is available on the market, the cost of the new medication will cut off his access to it. Because of these unresolved issues regarding treatment and access that are symptoms of medical neoliberalism, clinical trials cannot be said to provide sustained or sufficient health care at all.

Conclusion

By expanding our view of ethics to include contextual factors in clinical trial participation, the regulatory approach to protecting human subjects from harm can be redirected to challenge the status quo of health care in the U.S. Although health care and clinical trials have historically been seen as separate issues, they have been and continue to be intimately connected. An ethics of human subjects research that does not account for general access to health care is dangerously limited. Pharmaceutical clinical trials in the U.S. – and globally as well – cannot be fully ethical until social inequalities are recognized and mitigated through more expansive measures to protect human subjects. Universal health care may be our best defense in creating an ethical system of research and development. Even without such radical progressive change in the provision of health care in the U.S., it is clear that it is time for the bioethics debates occurring

in scholarship, the mainstream media, and public policy to contend with the impact of political and economic constraints upon ethical research practice. 

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