Beyond Economics: How Price Controls Are Killing Millions Of Patients

Due to maximum-wage policies, it currently takes about a decade for working medical therapies to reach patients. Stronger incentives in the clinical trial process responsible for the delays would leave product safety unaltered, but would save millions of lives.

Investigational research through clinical trials is an integral part of medical innovation, but unrecognized price controls in the process cause enormous harm to patients by prolonging trial recruitment. Lifting the price controls will speed up recruitment and limit the suffering of waiting patients without altering the standards of product safety mandated through the FDA.

The hidden price controls affects the clinical development phase of the biopharmaceutical approval process, involving three phases of clinical trials, that takes up the vast majority of the time from idea to market. Recent data from Tufts University indicate that clinical development takes about 9 out of the 10 years from entering the FDA approval process to market entry. The long development time is due to the length of time to complete the clinical trials, which in turn is due to the long recruitment process of trial doctors and subjects.

Doctors and subjects participating in trials do so mainly to help the patient get on a better therapy as a last resort, when failing on standard care. However, a key additional benefit of their participation is that it provides a great public service by allowing future patients and providers to learn what works or not in health care. In economic jargon, trial participants confer "positive external effects" to future patients beyond their own benefit on getting on a potentially working therapy. It is widely held, and indeed reflected in many policies around the world, that such positive external effects should be subsidized in order to stimulate them. This is why we subsidize other activities with health risks that confer benefits to others not engaged in those activities. For example, this is the rationale for vaccine subsidies when those vaccinated could have infected others, or compensation for military services that involve health risks that potentially reduce similar terror-related health risks to the public. The societal value of such subsidies is that they beneficially compensate and raise the particular activity, paid for by those not engaged in the activity but benefitting from it.

However, subsidizing the participation in clinical development that benefits us all is exactly the opposite of what governments do. Indeed, government policies often amount to "taxing" rather than subsidizing such participation, by making both providers and subjects incur financial losses through trial participation or adding unnecessary red tape and regulations to the process. The main harm is mainly because of existing regulations that prohibit compensating doctors and subjects sufficiently for investigational research. These "maximum-wage" regulations stem historically from bio-ethicists who proclaim expertise in what's right or wrong behavior in health care. Their influence, although of course well-intended, is misguided and extremely harmful.

Moreover, ethical concerns about these particular activities seem very peculiar and ad hoc when compared to other areas where we allow similar forms of compensation. Are bio-ethicists also against compensating military personnel for undertaking health risks for the benefit of the health of the larger public? How about factory or construction workers or truck drivers that may induce disabilities or fatalities from dangerous work conditions? The point is not only that we allow compensation for health risks for the larger good on a daily basis already; the more important point is that these "moral costs" incurred by a few bystanders are eclipsed by the much larger benefits to the masses of future and current patients on both sides of the trade in investigational research.

Whenever prices are artificially held down through government controls, many more buyers than

sellers line up. The price controls implicit in banning compensation in investigational research is no exception. The controls have resulted in a classic excess demand for clinical trial data; there are far more studies seeking to recruit participants than there are providers and subjects interested in participating in them. This leads to queuing by the demand side as trials wait for a dismal 3 percent of the eligible patients currently estimated to participate in investigational research. Given that this queuing leads to at least a decade from idea to market, it seems safe to argue that relying only on the altruism of trial participants to teach us what works in health care is not getting the job done on time.

The lengthy recruitment process implied by these price controls could be remedied partly by allowing for financial "neutrality" in investigational research, at the very least. Such neutrality would involve the more modest goal of making subjects and providers at least not take a financial hit from participation, as opposed to being adequately compensated. Such neutrality would change the incentives of, say, oncologists, who currently earn thousands from putting a patient on a branded cancer drug, but lose money when their practice engages in trial work. It would also allow for compensation of subjects above and beyond simply not paying for the treatment investigated in a trial, but going beyond that. If not in cash, this could be potentially done through life insurance policies to family members, payment of health insurance premiums, or other types of incentive mechanisms.

With lifted price controls, future patients would ideally have a mechanism to pay current doctors and patients in a trial for the benefit of the learning generated. Ideally we would live in a world where future patients did not just free-ride off trial participants. It turns out that company-sponsored investigational research would enable this valuable compensation across patient generations. This is because the venture capital and private equity firms that fund the multiple rounds of new treatments naturally stare blindly at future earnings when deciding on supplying capital. Incentives in trials would thus be financed from these future earnings, which in turn would ultimately be paid for by patients on the new treatment when marketed. In economic jargon, corporate financing of trial incentives would "internalize" the positive externality of trial subjects by making those benefitting from the learning pay for it.

In addition, if price controls were lifted, the firms funding neutrality would be policed by their own success. Most Americans already have access to a wide range of safe and effective non-experimental treatments, and most have public or private insurance to pay for them. So why would they enroll in a trial for a new therapy that may not work, when they have access to the newest therapy that does? This is partly why trials are currently going abroad from the US to other countries where no care is available outside the trial. But this also implies that lifting maximum wage policies would in effect police companies to provide relatively stronger incentives, when it would have the greatest value in generating speed.

Naturally, there may be limited abuses of a financial neutrality system, just as there are abuses of the current system today. These would need to be regulated. However, the harm imposed by such abuses would likely be miniscule compared to the benefit to the masses of patients getting working therapies sooner without sacrificing FDA standards on product quality. In particular, a future system would need to clearly separate the two issues of compensation and consent. The horrific practices of forced participation in the German Nazi trials, or the deceptive practices of the well-known US Tuskegee syphilis experiment resulted in much-needed ethical oversight of the conduct of trials. However, these were failures in adequate consent and not compensation. Indeed, there is a useful role for public oversight of consent in an area where health risks may be involved, but those risks may be hard to evaluate. Certainly consent, in conjunction with health risks, has been effectively regulated in many other contexts. It is successfully addressed not only in vaccine programs through the HHS, or the military through the DOD, but also in other areas such as occupational safety through OSHA, or in any of the local police or fire departments throughout the country. Compensation for health risks in the presence of regulated consent is

certainly feasible in investigational research as well.

In summary, the government needs to get out of the way of allowing future patients to incentivize people in medical development for the knowledge they provide. It can take a step in the right direction by at least allowing financial neutrality in investigational research, while retaining strong consent regulations. Doing so would not only justifiably compensate "trial-veterans" or their families for the great public service they provide, but would also prevent the silent killing of millions of patients waiting for working therapies as defined by current FDA standards.

ASSIGNMENT:

1. **To what extent do you agree with the articles economic point of view regarding price controls in the medical trial market? Explain in a detailed paragraph.**

2. **Create a supply demand graph that indicates accurately the problem the author sees currently in the market.**

3. **(a) Create a second supply demand graph that depicts the solution (ex subsidizing) of the medical drug trial market.**
   (b) How economically does this offer a better alternative. Explain using the differences in the two graphs you drew.