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## Working Paper

Some policy lessons from medical/therapeutic responses to the COVID-19 crisis: A rich research system for knowledge generation and dysfunctional institutions for its exploitation

LEM Working Paper Series, No. 2021/19

## Provided in Cooperation with:

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*Suggested Citation:* Dosi, Giovanni (2021) : Some policy lessons from medical/therapeutic responses to the COVID-19 crisis: A rich research system for knowledge generation and dysfunctional institutions for its exploitation, LEM Working Paper Series, No. 2021/19, Scuola Superiore Sant'Anna, Laboratory of Economics and Management (LEM), Pisa

This Version is available at:

<https://hdl.handle.net/10419/243515>

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# LEM

## WORKING PAPER SERIES

**Some policy lessons from  
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**2021/19**

**May 2021**

**ISSN(ONLINE) 2284-0400**

24 May 2021

***SOME POLICY LESSONS FROM  
MEDICAL/THERAPEUTIC RESPONSES TO  
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SYSTEM FOR KNOWLEDGE GENERATION  
AND DYSFUNCTIONAL INSTITUTIONS FOR  
ITS EXPLOITATION<sup>1</sup>***

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<sup>1</sup> This paper largely draws upon the contribution to the Interagency Task Team (IATT) Report for the 2021 United Nations' Multi-stakeholder Forum on Science, Technology and Innovation. The author thanks Richard Roehrl for his support; Fabrizio Chiodo, Ugo Pagano, and Caterina Sganga for their insights; and Benjamin Coriat, Andrea Roventini and Joe Stiglitz for very helpful comments. The author gratefully acknowledges the support from the European Union Horizon 2020 Research and Innovation programme under grant agreement No. 822781 – *GROWINPRO*. The usual disclaimer applies.

## ABSTRACT

This note discusses the medical/therapeutical responses to the COVID-19 pandemic and their “political economy” context.

First, the very quick development of several vaccines highlights the richness of the basic knowledge waiting for therapeutical exploitation. Such knowledge has largely originated in public or non-profit institutions.

Second, symmetrically, there is longer-term evidence that the private sector (essentially Big Pharma) has decreased its investment in basic research in general, and has long been uninterested in vaccines in particular. Only when flooded with an enormous amount of public money it became eager to undertake applied research, production scale-up and testing.

Third, the “political economy” of the underlying public-private relationship reveals a profound dysfunctionality with the public being unable to determine the rates and direction of innovation, but at the same time confined to the role of payer of first and last resort, with dire consequences for both advanced, and more so, developing countries.

Fourth, on normative grounds, measures like *ad hoc* patent waivers are certainly welcome, but this will not address the fundamental challenge, involving a deep reform of the Intellectual Property Rights regimes and their international protection (TRIPS Agreements).

## **Some policy lessons from medical/therapeutic responses to the COVID-19 Crisis: A rich research system for knowledge generation and dysfunctional institutions for its exploitation**

It is useful to distinguish between the direct and indirect impact of the COVID-19 pandemic. The former includes the epidemiological effects. We try to model them in Bellomo et al. (2020). The latter concern the effects of the institutional and policy responses to it. In turn, among such effects one may further distinguish the socio-economic impact of the measures of containment and mitigation. We discuss them with their deeply asymmetric implications among social classes and groups in Dosi, Fanti and Virgillito (2020). Finally, there are the medical/therapeutical responses. This note concerns them.

I shall, first, present some major “facts”; second, discuss some general lessons; and, third, offer some policy implications.

### ***1. Some medical/therapeutical facts revealed by the pandemic and the policy responses to it***

- (i) A few months after the identification of the COVID-19 virus at least eight vaccines have become available (Pfizer, Moderna, Astrazeneca, Sputnik V, Johnson and Johnson, Sinopharm, Sinovac, Covaxin) and at least seven others will be very soon (Curevac, Novavax, Convidicea, EpiVacCorona, and, from Cuba, Soberana, Abdala and Mambisa).

Normally, a vaccine takes years of research, development and testing. The quick results witness the availability of an extremely rich body of knowledge waiting for its therapeutic exploitation. It relates to several avenues of explorations, with already around sixty potential vaccines in the pipeline as of January 2021 (a thorough discussion is in Rawat et al, 2021). Many of them, but not all, are broadly associated with the Genetic Engineering paradigm, and, more specifically in our case, often associated with immunotherapies for cancer. And, indeed, some of the new vaccines (Pfizer, Moderna) were obtained by imaginative re-applications of mRNA studies originally concerning cancers.

- (ii) Equally striking is that such knowledge is largely originated in public or non-profit institutions (Oxford University, MIT, Harvard, Gamaleya Institute, University of

Mainz, public Cuban laboratories, etc.) and explored either there or in spin-offs thereof (e.g. BioNTech, Moderna).

This should not be surprising. Basic research is almost entirely supported and often also performed by the public sector in both Europe and the USA. So, for example, in the USA, *all* 210 New Chemical Entities (NCEs) approved by the FDA in the period 2010-2016 got funding, to different degrees, from the National Institutes of Health (NIH) (Cleary et al., 2018).

Symmetrically, there is longer-term evidence that the private sector (essentially Big Pharma) decreased its investment in basic research, as witnessed by the diluted output of scientific papers cited in patent applications (Arora et al. 2018).

Therefore, it is not surprising that Big Pharma has been found largely unprepared, at least concerning basic knowledge on vaccines. Among the New Molecular Entities approved by the Food and Drug Administration (FDA) since the year 2000, less than 6 % concerned antibiotics or anti-viral drugs (Walker, 2020).

And attention to vaccines has always been low. Even the Public/Private Initiative concerning AIDS vaccines which had raised many hopes (cf. Chataway et al., 2007) failed. Vaccines for AIDS, or later Ebola were never developed. After all, they concerned “special groups” or poor populations. It is more rewarding to invest in cures which ideally make chronic otherwise acute diseases (*docet* the anti-retroviral drugs for AIDS). But, of course, the business is different for a virus which is quite egalitarian in terms of national per capita incomes and social classes (of the infected, not of the casualties).

In this case, the whole private sector has immediately been eager to undertake focused applied research, production scale-up and population testing in exchange for an enormous amount of financial transfers.<sup>2</sup> Approximate estimates suggest 8 billion euros from the European Union and around 18 billion US\$ in the States. Nobody knows exactly for what: Research? Manufacturing? Testing? Advance payment of the vaccine themselves?<sup>3</sup>

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<sup>2</sup> Note that this represents a major discontinuity *vis-à-vis* the historical record of anti-flu vaccines usually developed under a regime of open science.

<sup>3</sup> Incidentally, notice that also some patents crucial for mRNA techniques have a *public* origin and are detained by *public* institutions (e.g. University of Texas and the National Institute of Allergy and Infectious Diseases -NIAID- of the National Institutes of Health).

Come as it may, even the developed Western societies ended up so far rationed in the vaccine supply – with the exception of the USA and Israel, let alone the disastrous conditions of the developing world – including India, which, incidentally, produces around 40% of the world vaccine supply.

- (iii) The “political economy” of the public-private relationship revealed by the policy responses to the pandemic generally highlights governments and regional institutions most often (voluntarily?) hostages of Big Pharma, at gun point. The few countries not rationed have been those giving up any bargain (“Tell me what you want and I will give it to you, and more...”), even at the expense of others, with also the EU losing despite signing pathetic contracts of the type “I will do my best to deliver, if nothing adverse happens...”.

Here, we are well beyond the “regulatory capture”: it is the reversal of the relationship between the State and the private actors, enshrined even in the most pro-market constitutions.

In this respect, however, there is a major difference between the European Union (and its Member States), on the one hand, and the United States, on the other.

The EU epitomizes the complete abdication of public authorities from their functions (basically telling private actors “do whatever you deem appropriate, in exchange for whatever you ask...”).

The United States, on the contrary, have kept in place a thorough system of command and control within the framework of the *Defense Production Act of 1950* (Pub.L. 81–774) which authorizes the President to order the production and distribution of goods and equipment and to requisition properties deemed necessary for national security, written large: the Act has been repeatedly invoked in reference to COVID-19 by both Presidents Trump and Biden. Failure to comply is a federal felony.

More specifically, regarding pandemics and other health-related threats, the *Pandemic and All-Hazards Preparedness and Advancing Innovation Act* (PAHPAI, Pub.L. 116-22) of 2019, expanding the *Pandemic and All-Hazards Preparedness Act* (PAHPA, Pub.L. 109-417) of 2006, establishes a system of responses whose philosophy is a comprehensive mix of compulsory provisions and allocation of resources to the private sector in order to comply. One of the main instruments is the *Biomedical Advanced Research and Development Authority* (BARDA), established in 2006 under the PAHPA, which has

been, for example, the main vehicle for the transfer of the roughly 18 billion US\$ mentioned above.

Essentially, the United States represent a model whereby the fighting of wars is privatized to mercenaries – which I consider bad enough – but the State keeps the authority of setting objectives and strategies. The EU gave up on all that: the philosophy is basically the equivalent to allocating money to recruit mercenaries to *fight whatever war they themselves decide*, and without even the compulsory task of winning it! (Because “the market knows better...”)

- (iv) The Developing Societies are, by and large, in much weaker conditions, often lacking any competent, incorrupt bureaucracy – decimated in its number by the policies stemming from the “Washington Consensus”, but not improved in its integrity. Only a few out of them have the manufacturing capabilities to make vaccines under license, and even fewer feel the political power to invoke articles 27, 31 and 73 of the TRIPS agreements permitting exceptions to IPR sales with compulsory licenses in the case of health and security crises.
- (v) Last, but not least, the pandemic crisis has dramatically highlighted the damages of the neglect, or, in some countries, the retreat by the State from a *universal public good – health*, and the corresponding extension of the market domain (more in Nelson, 2005).

The scenes of serious patients unable to reach hospitals is unfortunately common in developing countries, but the pandemic has shown the policy-induced scarcity of public services also in developed ones. Even in the “civilized” Europe, the author of these notes will always remember the long trail of army trucks bringing the bodies of the victims of such market-inspired negligence to crematories in other regions because burning was at full capacity in Lombardy.

## **2. And some general lessons**

- (i) This pandemic will not be the last one. It is a profound sign of the changes in the relationship between humankind and nature which occurred after the Industrial Revolution and rapidly accelerated over the last half century. Some scholars go as far as saying that we have entered the *Anthropocene* (Coriat, 2020; Crutzen, 2006).



For sure the destruction of biodiversity, the elimination of any distance between wild and human habitats, the exponential increase in the industrial farming of animals – such as poultry – are all recipes for culture of viruses and bacteria mutations and their quick transmission to humans.

- (ii) Even if vaccines are an ex-post mitigation and not a long-term answer, advanced societies, let alone developing ones, turned out to be largely unprepared.

The fundamental reason is the deeply dysfunctional relationship between the private and the public in the generation and exploitation of innovative knowledge, in our case of health-related knowledge.

And, in turn, the dysfunctionality rests upon the extent, depth and distribution of Intellectual Property Rights.

In brief:

(a) The Bayh-Dole Act (1980) in the USA, and imitations in other countries, including the EU, -allowing patentability of the outcome of publicly funded research -, tends to distort the efforts of search of e.g. universities, which should be mainly *curiosity-driven*. (Fortunately, the evidence supports that, at least in top universities, such distortion has not been too deep, but the risk is always there).

(b) As a cascade, public institutions generate promising “basic” knowledge which is then sold generally at ridiculous prices to Big Pharma or incorporated into spin-offs which might generate enormous rents to successful academics.

(c) Next come testing in vitro and finally on humans. Note here the potential conflict of interest involved in a process whereby drug companies test their own products.<sup>4</sup>

(d) At the end, it is the public which continues to support fundamental research, while it is ultimately Big Pharma which masters *the rates and directions of innovative activities*.

(e) Finally, drugs and vaccines are sold back, directly or indirectly, to the public at prices which have little to do with either the *private* costs of search or the costs of production.

- (iii) It is often said that against the “the fight against the pandemic is a war”. If it is, and I believe it is, *wars are too serious a business to be left to the markets*. During WWII, the USA

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<sup>4</sup> Typically this is also done for the majority of drugs based on ridiculously low number of treated and placebo subjects, on the grounds of very weak statistical tests. Vaccines are an exception, and in the case of Covid-19 testing has become intermixed with a sort of pre-sale marketing.

had become, for very good reasons, a nearly full centrally planned economy. After roughly three months after Pearl Harbor it was capable of producing circa a tank per hour (more in Gross and Sampat, 2020 and 2021, and Best and Bradley, 2020). Conversely, after the COVID-19 outbreak California received with delays a largely insufficient number of *faulty* testing kits; after three months the Italian government was unable even to map who was able to produce masks (personal experience); all over the developed West ventilation emergency devices have been scarce for months; and the list could continue...

### ***3. Some policy lessons***

Some of them, the most fundamental, are long-term.

The ‘illusion of control over nature’, and the use of *nature as a sink* (Brock and Taylor, 2005) must be reversed before it is too late: putting it in a shorthand, burning forests in the Amazon and destroying rainforests in Indonesia is closely related to the health of humankind.

Equally important, health must become a *universal human right*, and knowledge concerning health is a *global common good*.

Operationally:

- (i) The crisis has shown the deep pitfalls of a health system partly or nearly fully left to the market. If health is a universal right, this must be taken care of by the public as much as, say, justice or public security.
- (ii) On the contrary, even when there is a universal health coverage, like in most European countries, public hospitals have been often the prime victim of austerity policies. This must be urgently reversed. What is needed is a massive increase everywhere in the world of the overall public expenditure for the health system and the strengthening of local hospitals and laboratories: a capillary hospital system is able to cope with widespread diseases.
- (iii) Basic health-related research is part of a “global war mission”, thus *not* subject to the mean calculation of “cost-benefit analysis” by economists!

- (iv) The States need to gain/recover the knowledge of what is produced, and what is “potentially known” in the country, and by whom (This is needed for even timid forms of ‘indicative planning’).
- (v) During crises like the current one it should be obvious that vaccines must be made available to the entire population of the world. A necessary condition is the possibility of manufacturing it everywhere one is capable. This in turn demands *generalized compulsory licensing*.

More fundamentally, in the near future, it is crucial to reform the prevailing system of protection of Intellectual Property Rights (IPR) and its international projection via the TRIPS agreements within the World Trade Organization (WTO). As we argue at greater length in Dosi and Stiglitz (2014), it is bad for science in Developed countries, for Global science, and for the economies of both developed and developing countries alike. It has been designed not to maximize innovation but rents for those who have had the good luck of receiving a patent (and the two are not the same).

While the evidence that IPR *in general* promotes innovation is far from convincing, there is good evidence that there may be adverse effects, especially with poorly designed “tight” IPR regimes: access to life-saving medicines may be restricted and so too access to knowledge that is necessary for successful development, and even for follow-on innovation. As governments have to spend more money to purchase the drugs they need, because of reduced availability of low-cost generic medicines, other expenditures—from those necessary to promote growth to those devoted to alleviating poverty—are reduced. Conversely, there may be perverse links between IPR protection and income distribution.

In some circumstances, such as in the pharmaceutical industry, the evidence is particularly striking. Before TRIPS, generics obtained under loose IPR regimes were able to dramatically reduce the cost of drugs available to developing countries. A vivid illustration concerns antiretroviral drugs against the HIV virus where generics were able to reduce the cost by between 98 per cent and 70 per cent. (cf. Coriat et al., 2006; and So et al., 2014).

Especially in the case of pharmaceuticals, where patents are indeed a major mechanism of rent appropriation, I propose that the public, which, to repeat, finances and performs most of the Phase I of research, ought to move all the way to phase III (i.e. experimentation on humans),

and when successful, transfer to Big Pharma, on nonexclusive base, the license to produce – which at that point should yield costs and thus prices not be too different from marginal costs.<sup>5</sup>

There would be three major gains.

First, the public would regain the control over the search priorities, that is on the rates and directions of innovative activities.

Second, it would certainly be a reform at massive *negative* costs for the collectivity.

Third, it would be a major equalizer in the access to lifesaving drugs between developed and developing countries.

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<sup>5</sup> By the time I finished this note – May 24, 2021 – President Biden has proposed a waiver on patents related to COVID-19 vaccines. This is certainly not the solution of the general problem of IPR in pharmaceuticals, but can be a significant step in the right direction.

Many of the reactions are disarming. A few commentators argue, first, that the waiver would be ineffective for most developing countries because they do not possess the tacit knowledge to produce vaccines even in absence of patents, and, second, that the waiver would be a bad precedent decreasing the incentives for Big Pharma to do research. Of course, both points cannot apply together! (Ugo Pagano has repeatedly pointed it out).

In the substance, the first point is certainly true, but this just reinforces the argument in favour of the development of local technological capabilities – Cuban style. The second is strikingly false, in general (cf. above, and the discussions in Cimoli et al., 2014; Angell, 2004; Dosi and Stiglitz, 2014), and with reference to vaccines in particular. The pharmaceutical industry has a historic record of negligible interest in vaccines and it will turn to this neglect, unless flooded by public resources, in terms of both knowledge and money. For sure, proposals like Biden’s trigger the “generosity” of Big Pharma, offering billions of doses at lower prices. Personally, I am all in favour of universal rights rather than pre-modern charity.

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