

crisis revealed the weaknesses of the US social system compared to Europe, and the mismanagement of the pandemic by the Trump Administration. Nonetheless, together with Congress, the Trump Administration pursued a determined and aggressive strategy to: (i) ensure US leadership in vaccine R&D, and (ii) secure supplies of future vaccines for US citizens.

Although the European Commission took the lead in negotiating advance purchase agreements with vaccine manufacturers on behalf of the 27 EU countries, and decided to provide loans to European biotechs engaged in vaccine development through the European Investment Bank, it fell short in terms of matching the US effort to incentivise vaccine innovation. This was because of a lower level of financial investment and insufficient coordination of research and innovation funding schemes (reflecting the more decentralised nature of R&D and health policies in Europe).

2.1 General considerations

Considering the race for a successful 'global product', a natural question concerns the optimal degree of competition and coordination. For COVID-19 vaccines, we observed an interesting mix of the two: although political authorities in China initially denied the upcoming disaster, Chinese scientists have been very open about their research results. In fact, the first vaccines to be authorised could be developed rapidly because Chinese scientists had published the genetic sequence of the virus as soon as it was deciphered, allowing universities and private firms, large and small, to compete aggressively to be the first in the race for a vaccine, with the help of private, and especially state, funding sources.

From the perspective of world welfare, the cooperation/open science part is obviously good. As for the competition on vaccine development, things are more subtle: on the one hand, more financial effort overall is good since it saves lives and accelerates exit from costly lockdowns. On the other hand, is there a risk of money being 'wasted'

in funding more than 100 vaccine projects, including advance building of production facilities? As discussed by Bolton and Farrell (1990), in “*times of war*”, speed is essential, and more coordination is preferable to “*fine-tuning for the most efficient option*,” if such an optimal solution comes significantly later. We can, however, safely conclude that speed has not been hampered, given the rush we observed. If anything, the risk to be worried about concerned ‘cutting corners’ in excessively fast approval of vaccines that might not be safe or effective enough. But that risk appears to have been dealt with successfully, since more than 13 billion vaccine doses had been administered worldwide by February 2023, with few adverse side-effects. Authorisation bodies (Food and Drug Administration (FDA) in the US, European Medicines Agency (EMA) in the EU, etc) thus showed they were able to combine speed and safety.

2.2 *The US versus the EU*

As is well-known, the US is a clear leader in biotech innovation (see evidence summarised in Aghion *et al*, 2020). Moreover, it set up an articulated US-centric COVID-19 strategy – Operation Warp Speed (OWS) – which took advantage of the complementarity between developing vaccines and securing advanced supplies. It thereby brought together the two phases of negotiations with private entities, while relying on the combined expertise and financial weight of existing federal instruments, in particular the National Institutes of Health (NIH) and the Biomedical Advanced Research and Development Authority (BARDA). This gave the US a first-mover advantage.

Congress allocated almost \$10 billion to OWS, of which more than \$6.5 billion was allocated to BARDA and \$3 billion for NIH research.

performance was quite impressive. And it is striking that, of the ‘big four’ pre-COVID-19 vaccine players – MSD, GSK, Sano and P zer – only the last emerged as a ‘winner’ of this race, and only thanks to its alliance with BioNTech.

Coming back to OWS, as stressed in 2020 by Moncef Slaoui¹²⁵, who was appointed OWS Chief Scientific Officer, there was a conscious decision to concentrate funding on three different technologies and two projects per technology (or ‘dual sourcing’): BioNTech/P zer (Germany/US) and Moderna (US) for the mRNA technology, Johnson and Johnson (US) and Oxford/AstraZeneca (UK/Sweden) for the viral vector technology, and Novavax (US) and Sano /GSK (France/UK) for the protein subunit technology.

It is hard not to consider OWS as an overwhelming success of ‘industrial policy’, bringing together, as stressed by Slaoui: (i) significant public money, (ii) competences from the whole ‘ecosystem’: universities, BARDA, NIH, FDA, biotech companies, big pharma, and even the US Army, and (iii) a small united decision-making structure to speed things up, at arm’s length from politics. Of course, there was quite some luck: the most successful technology, mRNA, was readily available, thanks to years of research efforts (which, as argued by Veugelers (2021) had not benefited before COVID-19 from the support it deserved). And the vaccines turned out to be even more successful than what could have been expected. But still, this episode was a great success, which other jurisdictions should definitely try to learn from.

2.3 For an integrated EU treatment and vaccine development strategy

Europe (especially when adding the United Kingdom and Switzerland to the EU) is strong in health, with its universities, biotech companies, big pharma companies and public money, which is ample although

125 See Jean-François Munster, ‘Moncef Slaoui au «Soir»: «Avec les vaccins, on va pouvoir contrôler cette pandémie», *Le Soir*, 26 December 2020, <https://www.lesoir.be/345671/article/2020-12-26/moncef-slaoui-au-soir-avec-les-vaccins-va-pouvoir-controler-cette-pandemie>.

scattered (the EU being rightly seen as a regulatory giant but a budgetary

equivalent of the NIH is worth considering. And the US has been able to use the leverage of the Defense Production Act to request private firm cooperation with OWS (not to mention the help of the US Army). The lessons of this US success are thus wide-ranging.

3 Securing supplies and setting up delivery systems

COVID-19 vaccines provided an opportunity for the European Commission to centralise discussions with vaccine producers in order to obtain sufficient vaccine supplies at an appropriate price.

The Commission was criticised in the first months of 2021 for insisting too much on low prices in their contractual negotiations with vaccine producers, and not enough on speed of delivery, in a world where the opportunity cost of delaying the recovery was huge. This criticism is not unfair, and countries including Israel, the UK and the US did get ahead of the EU in vaccination in the first half of 2021. This was particularly true in the first quarter of 2021. In this respect, while the UK and the US benefited from their close links with, respectively, AstraZeneca and Pfizer and Moderna to accelerate purchases, Israel showed that one does not have to be involved in R&D or production to be the first in terms of purchases: paying a high price is enough (Israel also allowed Pfizer/BioNTech to analyse in detail the impact of vaccination on the Israeli population, thereby contributing to global knowledge). Indeed, Israel seems to have paid between \$47 and (more than) \$100 – respectively around €38 and €81 at the time – for two doses of the Pfizer/BioNTech vaccine¹, much more than the €24 the EU paid for the same vaccine (the EU also paid less than €4 for two doses of the AstraZeneca vaccine and €36 for two doses of the Moderna vaccine in the original contracts signed by the Commission (these numbers are contractually meant to be secret but were disclosed in a tweet by the Belgian secretary of state for budget).

After the first quarter of 2021, EU vaccination took off and many

127 Stuart Winer, 'Israel has spent \$788m on vaccines, could double sum — Health Ministry', *Times of Israel*, 16 March 2021, <https://www.timesofisrael.com/israel-has-spent-788m-on-vaccines-could-double-that-in-future-health-ministry/>.

western EU countries overtook the US, the UK and Israel in vaccination rates. And the Commission intervention favoured equal treatment between member states, while earlier a group of four countries (France, Italy, Germany and the Netherlands) had decided to join forces and bargain only for themselves. Thanks to the Commission, everyone agreed ultimately to go for centralised EU-wide bargaining.

As discussed by Dewatripont (2022), vaccination rates went up with little variance across most EU countries in the first months of 2021. Until May 2021, only Bulgaria was significantly slower than the other EU countries. During the course of May and June, some other eastern EU countries, including Romania, Slovakia, Poland and Czechia, also started to lag the rest of the pack. Other EU countries stayed close together until June, when divergence started to grow. But by this time, vaccine hesitancy had become the key constraint, not vaccine availability or logistical challenges. Joint European purchases therefore ensured equity between EU member states, a success which explains why HERA was subsequently tasked to buy monkeypox vaccines for most EU countries.

'not a normal price like we typically get for a vaccine—\$150, \$175 per dose. So, pandemic pricing'¹.

is should remind authorities of the need to avoid rents above competitive rates of returns for vaccines and treatments. e question

even leading to adverse macroeconomic consequences (see, for example, the discussion in Aghion *et al*, 2021). In this respect, one should reiterate that industrial policy should be competition-friendly, as stressed by Aghion *et al* (2015) and as successfully managed by OWS.

Moreover, not only is the equilibrium $(B - C)$ 3 percent per year too high, but evidence points to an authorisation bias against 'truly creative' innovation through an excessive reward of 'marginal' innovation: Fojo *et al* (2014) looked at US evidence on cancer therapies and stressed the unintended consequences of expensive marginal therapies that earn higher risk-adjusted returns than more innovative ones, and are unsurprisingly pursued by for-profit pharma companies. This indicates a flaw in the authorisation/pricing process for new therapies, since by making marginal innovation more lucrative, one raises the opportunity cost $(B - C)^*$ of engaging in truly innovative research. Industrial policy should try and address this problem.

4.2 Improving the innovation/affordability tradeoff

Unsurprisingly, the COVID-19 vaccine experience has generated debates about the distribution of the rewards of innovation between private companies and the public sector.

4.2.1 Improving bargaining positions

In fact, the emergence of the European Commission as a negotiator on behalf of the 27 EU countries echoes efforts by groups of EU countries to join forces in price negotiations with drug companies. Belgium, the Netherlands, Austria, Ireland and Luxembourg were the first such group¹⁰. Other initiatives are the Valletta group of southern European countries, the Nordic pharmaceuticals forum and the Visegrad group¹¹.

130 See <https://beneluxa.org/>.

131 Francesca Bruce, 'Europe's Biggest Multi-Country Access Alliance Picks Up the Pace', *Pink Sheet*, 28 July 2021, <https://pink.pharmaintelligence.informa.com/>

the goal of such initiatives is to put these countries in a better position to require more transparency about R&D, manufacturing and distribution costs of the drug.

Truly meaningful impact would however require further coordination. The COVID-19 vaccine episode should provide an opportunity to go more generally towards EU-wide coordination of negotiations with pharma companies, to limit their ability to put states in competition. Kyle (2007) showed in particular that new drugs are introduced earlier in jurisdictions that pay higher prices, which is in line with the priority given to Israel by Pfizer. One should therefore not draw the wrong lessons from the European COVID-19 negotiation: it should constitute a precedent worth building on in order to improve the bargaining power of European member states with pharma companies.

Rare diseases would be a natural area for EU-wide intervention. One objective reason for high prices is of course the limited market size of each country. A pan-EU purchase would offer the prospect of higher sales, thereby making lower prices more sustainable for industry. One could even envisage advance market commitments, like with vaccines (Levin *et al*, 2021), which should ideally be coupled with a percentage of profits to be refunded by the company in case these turn out to be higher than expected.

EU-wide coordination of the organisation of statistically significant clinical trials, which does represent a key challenge for rare diseases, would also make sense. And the same is true for the necessary coordination of national research and development funding beyond EU R&D funding, along the lines of NIH funding, in order to maximise synergies, especially for rare diseases.

Finally, COVID-19 vaccines are an extreme example of the asymmetric timing of the financial costs and benefits of health innovation. Early stages of the process are heavily subsidized – in this case not only R&D but even production – but price negotiations, and especially renegotiations, happen later on and risk insufficiently rewarding earlier subsidies through subsequent price discounts in the case of

successful innovation. Public authorities should make their early support conditional on profit-sharing schemes in order to benefit from the upside of innovation.

4.2.2 Governance

Current healthcare innovation typically works as follows: its later stages are implemented by the private sector, often big pharmaceutical companies, which buy biotech firms, which are themselves built on publicly-funded research (universities, the NIH and BARDA in the US, etc). While this sequence is natural, achieving a fair distribution of the rewards of innovation is difficult in a system of large for-profit providers of new vaccines and therapies. The profit motive is a powerful driver with high rent-extraction costs, and economics has documented how information asymmetries and residual rights of control do allow producers to earn rents. One idea to limit these rents could be the introduction of common-good advocates on the boards of pharma companies. Another could be to transform (part of) them into 'benefit corporations', as advocated by Fischer *et al* (2019), so that shareholder value would stop being their overriding objective (an objective resulting from their legal charter and, since the 1980s, aggressively put into practice).

Change could be enacted by leveraging companies' corporate social responsibility. Concretely, payers could for example incentivise companies involved in expensive therapies to create *ad-hoc* subsidiaries for these activities and organise them according to the benefit corporation concept (Cummings, 2012) in order to subsequently obtain a B Corporation certification¹. The benefit corporation declaration gives legal protection to companies to pursue social and environmental performance alongside value for shareholders. The boards of benefit corporations are required in their decision-making to consider other stakeholders in addition to shareholders. The application for B corporation certification further enhances accountability to social good, as the

132 See <https://bcorporation.net/>.

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