Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

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Editorial

Determining the obligations of the pharmaceutical industry during the pandemic

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The scale and severity of the coronavirus 2019 pandemic requires a coordinated response from many parts of society. In broad terms, the social response aims to limit—and, to the extent possible, redress—the effect of the pandemic on health and economic outcomes. The success of the coordinated response requires a level of consensus on overall objectives and clarity regarding the individual responsibilities of each of the actors. Key ethical questions arise in any attempt to define specific health and economic objectives. How should the benefits and costs of the response to the pandemic be distributed? What obligations do the different parties have? How are these obligations determined? Several papers have sought to address the fair distribution of benefits and costs in the global allocation of vaccines [1–3]. Recently, Emanuel et al. [4] sought to determine the ethical obligations of pharmaceutical companies in response to the pandemic.

Emanuel et al. propose four principles for pharmaceutical companies producing and distributing COVID-19 vaccines: (i) optimise vaccine production to reduce health and economic burdens; (ii) distribute vaccines fairly in accordance with need; (iii) ensure the activities are sustainable in the long-term, and (iv) ensure accountability in decision-making. The authors suggest the approach that is likely to best meet these principles combines some degree of centralised procurement and distribution (along the lines of the COVAX arrangements [5]) with transparent bilateral deals, tiered pricing and appropriately remunerated knowledge transfer. This structure aligns with what is currently happening, at least in broad terms. Perhaps more controversial are the ethical obligations that Emanuel et al. propose pharmaceutical companies have (and be held to). Specifically, Emanuel et al. argue that pharmaceutical companies are ethically obligated to ensure equitable vaccine distribution in a manner that optimises health and economic outcomes.

A fair distribution of vaccines that appropriately optimises health and economic outcomes is a good outcome. Debate is more likely to focus on the specific details of achieving the goal rather than the goal itself. Meeting such a social goal, however, is not typically an ethical *obligation* of the pharmaceutical industry. It is ethically praiseworthy when pharmaceutical companies contribute meaningfully to such a goal, and ethically blameworthy when the actions of a pharmaceutical company actively undermine this goal, but to define the obligations of pharmaceutical companies in terms of this goal goes a step further and requires an explicit argument. We examine the argument Emanuel et al. provide, highlight some of the tensions in this argument and (briefly) consider an alternative approach that nonetheless aims to achieve similar social goals.

The argument provided by Emanuel et al. has two key components. First, the health and economic objectives are those proposed by the Fair Priority Model [1]. The Fair Priority Model proposes three fundamental values: benefit people and limit harm, prioritise the disadvantaged and equal moral concern. The model follows this up with concrete guidance on how vaccines can be distributed in a way that fulfils these values. For Emanuel et al., the Fair Priority Model provides a standard by which the actions of pharmaceutical companies can be judged. Second, the justification for the additional obligations on pharmaceutical companies rests on special obligations that arise in an emergency [4]. The bases for these obligations are the pharmaceutical industry's "indispensable capacity to help to end the pandemic by developing, manufacturing and distributing COVID-19 vaccines" [4]. The Fair Priority Model provides a good way to define the health and economic objectives of vaccine allocation. The second component of Emanuel et al.'s argument is trickier.

Do pharmaceutical companies have an ethical obligation to ensure equitable vaccine allocation on the basis of their capacity to contribute? To some extent, the position taken by Emanuel et al. maps onto arguments in the ethical literature regarding our obligations to assist in emergencies [6]. Philosophers tend to ground intuitions regarding obligations in an emergency by appealing to cases that involve individuals with a capacity to help responding to a life-or-death situation. To borrow from one such case [7], it seems reasonable to suggest that if you are in a position to help a child drowning in a pond, you have an obligation to try and save the child even if your efforts are likely to incur some costs to you. The challenge for Emanuel et al. is to show how these same intuitions apply in the context of pharmaceutical companies responding to the pandemic.

It is not straightforward. Pharmaceutical companies are commercial entities with well-defined roles and functions

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(and ethical and legal responsibilities) in medical innovation. The emergency created by the pandemic is distributed globally and creates both immediate and long-term problems that differ between countries and identifiable groups within countries. And, critically, the pandemic requires action at multiple levels by many different parties. If Emanuel et al. are relying on standard arguments regarding our obligations in emergencies, their argument requires more detail than they currently provide. In particular, more consideration is required regarding the agreements that pharmaceutical companies entered into at the start of the pandemic to produce vaccines and other therapeutics.

The pandemic has changed the distribution of labour in funding pharmaceutical innovation. The pre-pandemic structure involved significant public funding for basic science research combined with significant private funding to undertake clinical drug development and to scale-up manufacturing in order to translate new discoveries from the basic sciences into a marketable medical product [8,9]. The urgent global need for vaccines and treatments for COVID-19 disrupted this model. There has been significant public, private and philanthropic investment and new models of cooperation between public–private, private–private and multilateral partnerships [10]. The social response to the pandemic has included the injection of considerable public funds from larger economies. In contrast with business as usual, a large proportion of public funds have been devoted to clinical drug development and production [8]. Additional support has been provided through advanced market commitments: typically bilateral agreements whereby governments, especially those from high-income countries, commit to purchasing high volumes at a set price.

In changing the funding mix, governments had the opportunity to negotiate expectations on pricing and distribution on successful development of vaccines. Examples of this include vaccine prices recognising funding contributions, bilateral agreements including proportional allocations to COVAX for distribution of vaccine to low-income countries, and some companies committing to not make a profit for the duration of the pandemic [11]. While mostly positive, these commitments fail to achieve fair distribution as determined by the Fair Priority Model [4]. Arguably, economies responsible for large financial contributions to vaccine development and production had an opportunity to shift the dial in a long-standing argument regarding what the public should expect from the contribution it makes to pharmaceutical innovation [12]. In the most part, public entities have not taken this opportunity. Indeed, in the US there has been concern regarding the types of contracts the government has entered into with pharmaceutical companies in terms of transparency and retaining protections for the public in terms of access [8,13].

What are the appropriate policy settings in a global public health emergency to stimulate rapid pharmaceutical innovation while ensuring adequate public control to achieve social goals? There are no easy answers to this question, and intuitions are likely to shift based where we locate ourselves within the pandemic, both temporally and geographically. We argue for two conclusions from these considerations. First, the obligations of pharmaceutical companies should be informed by the agreements put in place prior to the development of the vaccines. There should be more recognition of early agreements and the context in which they were made when determining the ethical obligations of pharmaceutical companies. The current context of the pandemic and where pharmaceutical companies have found themselves are also important, but these should not be the sole determinants.

Second, there are benefits to seeing the obligations proposed by Emanuel et al. as *societal* obligations rather than obligations that pharmaceutical companies need to shoulder alone. Responding to the pandemic is a collective action problem. The objectives proposed in the Fair Priority Model and the obligations proposed by Emanuel et al. are appropriate for the collective. Being clear on these objectives and the collective societal obligations to achieve these objectives allow us to further specify the obligations of the different parties. Some obligations are shared between public and private parties; others are more specific to a group due to the roles and functions the group contributes. A benefit of this approach is that most of the obligations for specific groups can be derived from existing regulatory requirements and social responsibilities. All parties, for example, have an obligation of transparency and accountability in decision-making. Specific (non-negotiable) obligations for pharmaceutical companies include research integrity and data sharing [14–16].

The response of health and medical research and pharmaceutical innovation to the COVID-19 pandemic has been remarkable. There is a collective social responsibility to ensure that the outcomes of this work are distributed to those most in need. While the obligations of pharmaceutical companies should be articulated in a different way, the principles outlined by Emanuel et al. provide helpful guidance for ensuring that public entities and the pharmaceutical industry adopt policies and practices that maximise health and economic outcomes fairly.

Conflict of interest

None.

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