

## Guest Editorial



# The Fragmented Nature of Pandemic Decision-making: A Comparative and Multilevel Legal Analysis

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The unfolding of the COVID-19 pandemic sheds light on the role that multiple legal and regulatory instruments play in a global emergency, whether at the international, regional or national level. Countries around the globe faced comparable challenges in responding to the pandemic crisis within the framework of their respective legal systems. While the need for international coordination has only increased, a variety of legal issues have also arisen distinctly depending on regional and national settings. It is against this background that the current *special issue* seeks to assume a simultaneously comparative and multilevel perspective to evaluate the different layers of pandemic decision-making.

The first article suggests casting a glance at the international and regional dimensions of fragmentation in pandemic governance. Pedro A. Villarreal, with his study on *Pandemics and Law: The Multilevel Dimension of Rules-Based Disease Surveillance*, reconstructs the information-sharing system of disease

surveillance beyond states. Information related to diseases with the potential for cross-border spread is a global public good. An ensuing question is how to ensure such information will be shared when events occur across different jurisdictions. Legally binding rules emerge as an option for ensuring authorities will share information on communicable disease outbreaks, and how. The contribution compares existing rules-based systems of *ad hoc* disease surveillance between states at the international and regional levels, namely the World Health Organization, the European Centre for Disease Prevention and Control, the Africa Centres for Disease Control and Prevention, and the West African Health Organisation.

Focusing on the European Union dimension, *Conditional Marketing Authorisation of Covid-19 Vaccines: A Critical Assessment under EU Law* by Alessandra Donati argues that conditional marketing authorisation of COVID-19 vaccines meets the conditions for being considered a precautionary measure, in line with the case-law of the Court of Justice of the European Union. These conditions are that the spread of COVID-19 poses a risk to public health and that there is a degree of uncertainty in the scientific data available at the moment of authorisation. Such conditions reflect the trade-off between two conflicting needs: the demand to speed up the authorisation procedure for the vaccines and their use, and the obligation to ensure their quality, safety and efficacy in compliance with EU law. Alessandra's article also identifies shortcomings in the risk assessment conducted by the European Medicines Agency and the risk management by the European Commission.

In her piece, *German State Aid for COVID-19 Medicinal Products: A Risk for Solidarity in the European Union*, Kristine Plank delves into the challenges to stronger European solidarity posed by national-level health policies financially supporting pharmaceutical companies. As the competencies in the field of health in the European Union are mainly devolved to Member States, it leads to situations where countries with a higher Gross Domestic Product may gain preferential access when procuring life-saving medicines. This risks undermining the solidarity across Member States so necessary when facing common health threats. Transferring more competencies in the field of health to the European Union could be a way of preventing self-defeating pandemic responses by national governments.

Different features of the fragmentation of decision making and governance also emerge within single national jurisdictions. Lauren Tonti, in *Symphony or Cacophony? Orchestrating Federal Mechanics toward COVID-19 Response in the United States & Germany*, argues that government structure affects public health responses by providing the channels through which pandemic mitigation measures are routed. While pandemics pose particular challenges for divided structures, division does not necessarily mean disaster. Comparing

how mitigation goals flow through channels of fragmented governance in two federal countries – Germany and the United States – the article illustrates both the mechanisms in play and the best practices in orchestrating them towards common health goals. By taking an evidence-informed approach, the author shows how federal systems can feature facilitators that unite and improve future pandemic responses.

A comparative approach is also taken by Irene Domenici and Franciska Engeser in their contribution *The Institutional Tragedy of Pandemic Triage Regulation in Italy and Germany*. When confronted with ‘tragic choices’ regarding the allocation of scarce intensive care resources during the current pandemic, both Italy and Germany showed an extremely fragmented decision-making structure, including individual hospitals, medical associations and recommendatory interdisciplinary bodies such as ethics councils. The article maintains that, in such a scenario, the legislature should play a key role in defining the normative framework for triage. It is the legislature’s duty to protect fundamental rights and provide a democratically legitimised normative and ethical framework. Central legislative intervention can also prevent fragmentation and thus uncertainty and discrimination.

The contribution by Christian Günther, *Legal vs Extra-Legal Responses to Public Health Emergencies*, argues against claims that emergency action through law is impossible or else doomed to be ineffective. The article challenges this position by shedding light on the response of many European states to the COVID-19 pandemic based on Lon Fuller’s theory of law. It explores several reasons why the fragmentation of governance between ordinary legal action and emergency extra-legal action is neither necessary nor desirable. European pandemic responses were intra-legal and, in that sense, unitary and effective. Ultimately, for liberal legal societies, there are special reasons for avoiding the legal/extra-legal divide as it impacts established values that contribute to the success of public health responses. Formal legal principles, as articulated in Fuller’s theory, are not only constraining but also a ‘liberating limitation’ allowing for effective, sustainable pandemic responses.

Lastly, Sofia Palmieri and Tom Goffin join the special issue as external contributors with their article *De Jure and De Facto: An Overview on the Italian Measures on Compulsory Vaccination*. They argue that, in Italy, compulsory vaccination for COVID-19 already existed as a *de facto* obligation before evolving into a *de jure* one. The article shows how the Italian government has created a comprehensive legal architecture in which citizens’ daily lives are defined by their vaccination status.

This brief showcase of this special issue illustrates how fragmented decision-making processes can be both enablers of, and obstacles to, effective pandemic responses. In several cases, such processes failed to respond to the sheer scale

of the COVID-19 pandemic and the need for uniform interventions. In others, the fragmented approach offered flexible and targeted solutions without jeopardising effectiveness and coherence. Ultimately, our project presents a multifaceted and nuanced appreciation of these dimensions. Yet, at a broader level, it also demonstrates that the challenges posed by the COVID-19 pandemic cannot be overcome by 'silo thinking', including in the legal field. An integrative legal approach involving several perspectives is patently necessary.

In the process of learning lessons from the international, regional and national responses to the COVID-19 pandemic, legal rules will inevitably come under close scrutiny. The acute nature of the threats posed by health emergencies entails that 'ordinary' decision-making mechanisms are not always sufficient. Exploring to what extent the different rules and mechanisms currently in force both constrain and enable rapid and efficient pandemic responses across levels of governance will be of the utmost concern. As COVID-19 perhaps moves towards becoming globally endemic,<sup>1</sup> incorporating insights from the pandemic phase covered under this *special issue* will be particularly beneficial for future public health emergencies or to other similar acute threats.

While the law is far from being the only variable leading to specific outcomes in infection and death rates, the contributions within show how it is certainly part of the broader equation. Exploring the legal determinants of health<sup>2</sup> is a pressing issue, both during and after pandemics. It is vitally important that the normative force of law be used to ensure that governments responding to pandemics and health emergencies maintain respect for the fundamental principles on which social relationships are based. The institutional and fundamental rights coordinates of democracies, both in Europe and beyond, are a value that must be safeguarded especially during times of threat and emergency. This is all the more important as there is burgeoning data showing how democratic standards are not necessarily an obstacle to an effective pandemic response.<sup>3</sup>

By analysing and assessing various fault lines and fragmentations in pandemic decision-making from a variety of perspectives, this special issue contributes to the future of improved pandemic preparedness and governance. It is the product of bringing together several legal approaches. Such collaboration would not have been possible without the support of the Max Planck Law

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- 1 Which does not necessarily mean it will be less severe. See A. Katzourakis, 'COVID-19: endemic doesn't mean harmless', *Nature* 601 (2022) 485.
  - 2 L. Gostin, 'The legal determinants of health: harnessing the power of law for global health and sustainable development', *The Lancet* 393 (10183) (2019) 1857–1910.
  - 3 A. Edgell, J. Lachapelle, A. Lüthmann and F. Maerz, 'Pandemic backsliding: Violations of democratic standards during Covid-19', *Social Science & Medicine* 285 (2021) 114244.

Network, which seeks to build bridges across different fields of law. We wish to thank Russell Miller and Gilbert Leung for their enthusiasm in fostering this huge undertaking. The guest editors and the authors are extremely grateful to Ulrich Becker and Armin von Bogdandy for their many valuable insights and sound guidance, and to the Max Planck Society for providing key support for making this issue fully open access.