# Integration through Expansive Unification: The Birth of the European Health Union

**Maurizio Ferrera,* Anna Kyriazi,† and Joan Miró‡**

*University of Milan, Italy
†University of Milan, Italy
‡Pompeu Fabra University, Spain; joan.miro@upf.edu

The coronavirus disease 2019 (COVID-19) pandemic pushed the European Union (EU) to centralize several public health functions. With the European Health Union (EHU) initiative, four reforms have been adopted to strengthen the EU's health security framework: the extension of the European Medicines Agency and the European Centre for Disease Prevention and Control's mandates, the creation of the Health Emergency Preparedness and Response Authority, and the upgrading of the Decision on serious cross-border threats to health. This article analyses the reconfiguration of authority patterns resulting from these reforms. It argues that the EHU exemplifies a distinct mode of integration (expansive unification) in which national sovereignty is not transferred *to* the center but is jointly exercised *at* the center. This mode of integration is suitable for capacity building in core state domains when functional needs confront reluctance from constituent units to surrender control.

The coronavirus disease 2019 (COVID-19) crisis marked a significant advance in the public health commitment and action of the European Union (EU). In the wake of a European Commission Communication of November 2020, important steps have been made towards the establishment of a European Health Union (EHU), an institutional framework mainly (though not only) aimed at addressing cross-border threats to health (European Commission 2020). The pre-existing instruments for managing preparedness, surveillance, risk assessment and common responses were extended and reinforced, while new bodies with delineated tasks and new procedures for declaring and managing a "public health emergency at Union level" were established.

In the EU, despite the strong functional pressures generated by the pandemic, authority centralization in public health policy could not be taken for granted. This domain qualifies as a "core state power" (Genschel and Jachtenfuchs 2016), as it is aimed at protecting the physical security of populations, and is therefore firmly associated with sovereignty, statehood, and national security. As with other core

*Publius: The Journal of Federalism*, 1–26
https://doi.org/10.1093/publius/pjae006

state policy fields, the upward delegation of authority to the EU level, and particularly to supranational institutions, has been limited and belated. At the beginning of the 1990s health policy was one of the least integrated sectors in the EU, with deeply entrenched national public health traditions standing in the way towards centralization (Lamping 2005). Indeed, in the early phase of the pandemic, even the simplest forms of coordination seemed elusive, as the Member States reacted with unilateral measures, blaming each other for the externalities of national decisions (Brooks et al. 2023: 789–729). This notwithstanding, by the end of 2023 the key pillars of the EHU plan had been put in place. In addition, such an authority reconfiguration was achieved quite rapidly, in the middle of the crisis: building the boat while sailing, as it were.

Our argument is that this relative institutional success is due to the specific mode of authority reconfiguration that has driven the construction of the EHU. On closer inspection, it becomes evident that national sovereignty over public health has not been transferred *to the center*; the EHU has been designed so that authority on public health can be jointly exercised *at the center*. Such a pattern goes much beyond the traditional intergovernmental method, based on Council negotiations; the exercise of joint authority within the EHU extends also to the executive and administrative arenas, that is, the traditional preserves of supranational bodies. The authoritative center of the EU has become more important, but also more crowded, formally incorporating representatives of the Member States in virtually all phases of the policy process. At the same time, supranational actors have also acquired new competences. We label this mode of integration "expansive unification," as its outcome is the creation of a unitary frame for expanding the overall amount of power of *both* supranational institutions and the Member States.

Existing studies analyzing the EHU have so far aimed to uncover the mechanisms through which the COVID-19 crisis became a catalyst for policy change, propelling new integration steps in the health policy domain (Brooks et al. 2023; Forman and Mossialos 2021). This literature has discussed the design of the different elements of the EHU initiative and their suitability to address the weaknesses revealed by the pandemic (e.g., Anderson, Forman, and Mossialos 2021; Beaussier and Cabane 2020; Deruelle and Engeli 2021). In this article we take a different approach, focusing on the following questions: what factors allowed the EU to rapidly centralize some key aspects of public health policy? And what pattern of authority has resulted from this centralization? For our analysis, we mobilize the analytical toolkit of federal theory to capture the distinctive nature of the EHU as an authority structure (see, e.g., Kelemen 2013; Benson and Jordan 2008, 2011).

Taking a federalism approach to analyzing the EHU provides a two-fold benefit. The analytical toolkit of federalism allows us to unravel the intricate web of intergovernmental relations and clearly identify the depth and boundaries of the vertical

separation of power in multi-level polities and policies. Under the federal lens, the EHU appears as an emblematic case of vertical codetermination resulting from a peculiar pattern of authority centralization, in which the powers of the constituent units and those of the supranational center are virtually "fused" together to produce binding decisions. Admittedly, the EHU lies at the extreme end of this authority pattern, which does characterize, however, other policy domains of the EU. We submit that the EHU case may be of interest also for federalism scholars, as it shows that, in certain types of compound polities, sharing *in* rule may blur the boundaries between self-rule and centralized rule, opening up unprecedented trajectories of political unification which are neither federal nor confederal.

The next section situates our study in the existing literature on the development of federal systems and EU public health. Subsequently, we elaborate an analytical framework for capturing the multidimensional nature of political authority in compound polities. This is followed by the reconstruction of the process which led to the launch of the EHU and the detailed characterization of the EHU, using official documents, complemented by press reports and secondary literature. Next, we discuss the causes and consequences of the expansive unification pattern, including empirical insights into the political process that led to it. The conclusion wraps up and links our findings to other pertinent literatures.

## Applying a Federalist Perspective to the EU

As noted by Vollaard, Van de Bovenkamp, and Martinsen (2016), the federal perspective appears particularly promising for understanding the interplay between functional and territorial politics and thus moves beyond the juxtaposition between intergovernmentalist and neofunctional interpretations of the EU. Virtually all contemporary democratic federations rest on variants of the cooperative blueprint, in which the constituent units share in the determination of federal policy in some key domains (typically including health policy: Fierlbeck and Palley 2015) and implement/administer federal laws (Mueller and Fenna 2022). Even in the presence of extensive co-determination, the maintenance of federalism (as a principle of political organization) requires, however, that the central government and the constituent units each preserve governing institutions and administrations of their own, in line with constitutional prescription on the vertical separation of power. This is the fundamental meaning of "shared rule": not necessarily sharing *in* rule, but the combination of self-rule (for the constituent units) and centralized rule, each enjoying some autonomy from the other (Fenna and Schnabel 2023). As we shall see, this tenet of federal theory will help us to overcome not only the intergovernmentalism/neofunctionalism dichotomy but also to pin down the distinctive character of the EHU in respect of the federal blueprint.

The EU is a hybrid political system, characterized by a mix of federal and confederal features (Fabbrini 2007, 2017). It is best described as a compound polity of nation-states (Ferrera, Kriesi, and Schelkle 2024), with the latter being, in turn, highly developed welfare states. EU building is a dynamic balancing act between "opening" inter-state boundaries (territorial and functional) to reap the advantages of economies of scale and preserving the "closure" conditions of nation-based welfare states, which uphold solidarity dispositions. In the field of health policy, the existence of large (but also diverse) health care systems at the national level has historically pre-empted ambitious attempts at centralization. In fact, the reluctance of the Member States towards competence delegation, as well as the absence of like-minded policy and societal actors advocating further health policy integration, have been pointed out as key factors to explain why health policy has remained one of the least likely cases of European integration (Vollaard and Martinsen 2017). Looked at from the perspective of comparative health federalism, the EU's institutional architecture shows, however, some serious structural flaws, as it subordinates health policy to the higher order constraints of the internal market and fiscal governance (Greer 2021). On this account, EU health policy seems to fit the patterns of the so-called new intergovernmentalism (Bickerton, Hodson, and Puetter 2015) of the post-Maastricht period, which sees Member States keen to enhance cooperation in new fields due to the supranational scale of functional challenges, while at the same time being reluctant to delegate sovereignty in politically sensitive "core state power" areas (Genschel and Jachtenfuchs 2016)—including health care.

EU competences in this domain have indeed remained limited over time, and Article 168 of the Treaty on the Functioning of the EU (TFEU) explicitly mandates the EU to respect national prerogatives regarding health policy and the organization and delivery of health care. There is however one domain in which—since 1992—the EU has "shared competences": public health, including the prevention of drugs-related health damage and monitoring, setting standards of quality and safety of organs and substances of human origin, and management of serious cross-border threats to health. Relying on these competences, the European Medicines Agency (EMA) and the European Centre for Disease Prevention and Control (ECDC) were established as independent EU agencies in 1995 and 2004, respectively. The former is responsible for medicine authorization, while the latter is charged with monitoring threats to human health from communicable diseases. In addition, the completion of the single market—based on the principles of free movement and non-discrimination—incentivized the emergence of a general framework for cross-border healthcare. In 1999, the DG SANCO (after 2014 renamed DG SANTE—Directorate General for Health and Food Safety) was established by augmenting the existing DG on consumer protection. Since then,

DG SANTE has become the leading policy actor on health policy dossiers as well as the main interlocutor for pressure groups acting in this field.

COVID-19 was not the first public health crisis affecting the EU. During the 2000s, the epidemics of SARS (2002), Swine Flu (2009), and E-Coli (2011) revealed a series of coordination failures. Thus in 2013 a Decision on Serious Cross-border Health Threats (European Union 2013) was adopted, defining the powers of the EU in transnational emergency situations. The Decision codified the ability of the Health Security Committee (HSC), the (until then) informal group convening health ministry representatives, to coordinate the national measures in response to outbreaks. It also established the Early Warning Response System (EWRS), a framework enabling the Commission and the competent national authorities to be in permanent communication for risk alert and assessment. The Decision also included a specific provision allowing the Member States to engage in joint procurement of medical countermeasures: the Joint Procurement Agreement (JPA) constitutes a centralized mechanism in which the Commission acts as a permanent secretariat and the Member States participate on a voluntary basis.

The outbreak of the COVID-19 pandemic in 2020 exposed the persisting weaknesses in the institutional architecture. The novel virus propagated internationally, with the features inherent to a transboundary crisis, but on a scale unprecedented in living memory. As in other compound polities, the EU found itself under immense pressure, but with an inadequate endowment of policy capacities, thus facing a much harder test than in earlier crises. The obvious transboundary character of the pandemic implied a net functionalist pressure to push authority towards higher levels of government (Greer, de Ruijter, and Brooks 2021). To pass the test, the EU embarked on a balancing act to reconfigure its authority structure, with a view to reconciling the need for centralization with the hard constraints posed by the Treaties and the reluctance of national governments.

## Authority Reconfigurations in Compound Polities

### A New Mode of Governance: Unification

The scholarly debate has analyzed the way in which the EU responded to the multidimensional crisis triggered by the COVID-19 pandemic through the general concept of coordination (Ladi and Wolff 2021: 327). We prefer to use the term "unification," which connotes the process whereby the Member States come "ever closer" to each other by means of creative institutional architectures (often—and increasingly—called "unions," precisely) empowering them to achieve common objectives, which could not be reached relying on national resources alone. Such architectures entail a wide range of possible unifying forms: not only coordination but also joint policymaking, common funding, the creation of new supranational

bodies, monitoring and mutual surveillance, the adoption of binding regulations, and so on.

Unification can play out in various arenas: legislative, executive, administrative, and judicial. A key—and poorly visible—instrument for unification has been, for example, the creation of special purpose committees comprising EU and national officers, with extensive formal powers in the adoption of implementing or delegated acts. In EU studies, the structure and functions of such administrative bodies are known as "comitology" (Türk 2015).

Unification patterns are shaped by several factors: Treaty rules, the nature of the pertinent issue and policy domain, problem and political pressures, path dependencies, the interplay, and negotiation between supranational and national institutions and so on. Federal theory attributes great importance to institutional details and invites exploration of the multi-level politics of their emergence as well as their effects on policy performance. The literature on cooperative federalism has extensively explored the structuring of intergovernmental relations under shared rule systems. The US debate has coined the bakery metaphor of "marble cake federalism" (Grodzins 1966) to describe the intermeshing of local, state, and federal governments in several policy domains, especially in social welfare and public works. While the term "cooperative" signals the presence of multiple forms of interplay and synergies across levels, there is a great variation in terms of dedicated channels, arenas, and institutions facilitating interaction and consensus building, both horizontally and vertically. The weakness of the cooperative infrastructure of the US (despite the marble cake) has been pointed out as one of the causes of the conflictual and poorly effective management of the pandemic in that country (Cigler 2021).

As we shall see, the marble cake metaphor is a particularly useful analytical lens for reconstructing the establishment and internal articulation of the EHU. Here the process of unification has generated a maze of (new) institutional bodies and arrangements linking supranational institutions and the Member States: a marble cake compared to which that of the US almost pales.

## Expanding Political Authority: A Positive Sum Process?

Unification is not only about the re-definition of tasks but also—and primarily—about the re-configuration of political authority. A full understanding of this second aspect requires a brief exercise of conceptualization: what are the constitutive components of an authority structure? And what is involved, exactly, in its reconfiguration?

The literature on political power (and authority, i.e., legitimate and formalized power) distinguishes between two dimensions: scope and infrastructure (Mann 1984). Scope defines the range of domains subject to authoritative decisions; infrastructure denotes the range of bodies which support decision-making and

execute decisions. We add two further dimensions, which have been highlighted by other scholars and are especially pertinent for our purposes: participation rights and constriction (Bartolini 2022: chapter 4; Zürn, Tokhi and Binder 2021). The former defines the circle of actors who are involved (in full or limited capacity) in the making of decisions. Constriction refers instead to the binding character, the prescriptiveness of decisions, for example, soft or hard.

Altering a given authority structure need not affect the four dimensions simultaneously. And, more importantly, it need not produce a zero-sum game among actors (Barnes 1988; Read 2012). As famously argued by Talcott Parsons, it is possible to extend the shares of power of a given unit "without sacrifice of the power of other units" (Parsons 1963: 258). Parsons conceived of power as the capacity to get things done (power to), but the later literature has brought into the picture also the notion of power "with": the combination of the power resources of different actors to maximize impact (Caputi 2013). The process of enlarging the scope of political authority to a new domain creates a greenfield in which existing or additional political actors can gain the right to participate in collective decision-making (thus increasing power), possibly supported by novel infrastructures. In fact, scope enlargement has a two-fold impact: it brings additional domains of social interaction under the reach of political authority and simultaneously assigns the "shares" of such authority to one or more designated actors. It must be noted however that, to remain legitimate, scope enlargements must take place "in the shadow of hierarchy", that is, under the rules of the extant authoritative status quo. When reconfiguring an authority structure, actors relate to each other with different endowments of power, understood both as power to/with and as power over (Pansardi and Bindi 2021).

We have mentioned above that the EU can be defined as a compound polity of national (welfare) states, in which authority reconfigurations inevitably entail balancing acts between supranational centralization and national autonomy. In the case of scope enlargements, compromises characterized by positive-sum arrangements are easier to forge, especially during hard times. We argue that the EHU represents an emblematic example of multidimensional and positive-sum authority expansion—a feature that we capture through the concept of "expansive unification."

## The Launch of the EHU

When the first wave of the COVID-19 pandemic hit Europe in early 2020, it exposed serious weaknesses in the EU's health security framework, particularly in two core tasks of crisis management: the detection of potential threats through data collection and analysis; and risk management through resource mobilization (Boin and Rhinard 2023). Firstly, in the domain of knowledge production, due to the

weak capacities for surveillance, risk assessment, and early warning, EU institutions were unable to swiftly detect, monitor, and alert on the evolution of the pandemic (Beaussier and Cabane 2020). The ECDC failed to warn Member States about the scale of the danger posed by the virus and its surveillance system remained hamstrung during the following months by the lack of comparable data and technical resources (European Ombudsman 2021). The absence of EU-level coordination was evident in the reliance by national governments on national experts as well as in the absence of supranational meta-analytical infrastructure and of coherent systems for sharing data and procedures.

In the domain of risk management and resource mobilization, several weaknesses emerged at both the national and the EU levels. Neither the EU nor individual Member States were able to ensure the supply of crisis-relevant medical countermeasures, such as drugs, devices, and biological products. They were incapable of effectively monitoring needs, while the lack of coordination among them in the supply of medical devices and medicines triggered shortages in many countries (Scholz 2021). In the Spring of 2020, this lack resulted in slow access, national hoarding, and competition in markets between Member States, and eventually in distorted prices (Scholz 2021). This happened despite the Member States having the possibility to use joint procurement. Although the HSC convened numerous times to discuss the responses in Member States, its limited competences and constriction capacities made it unable to coordinate national responses. Consequently, containment measures, including border closures, were implemented without EU-level coordination, while export restrictions were adopted by some Member States on personal protective equipment.

After the initial weeks of division among Member States European coordination increasingly found its way. Nonetheless, overall, policy responses to the COVID-19 pandemic within the EU were reactive, fragmented, and ad hoc. Consequently, various EU actors called for reinforcing the European health policy framework, including sectoral interest group organizations (e.g., European Public Health Alliance 2020, European Patients Forum 2020, EU4Health 2020), the European Parliament (European Parliament 2020), the Trio Presidency within the Council of Ministers, constituted in 2020 by Germany, Portugal, and Slovenia, and groupings of Member States (*Politico* 2020). On the front of public attitudes, the reluctance that had hitherto impeded the robust involvement of the EU in healthcare prior to the pandemic (Vollaard and Martinsen 2017: 340) gave way to increased levels of support (Zalc and Maillard 2020).

As a response, in November 2020 the Commission presented its Communication on "Building a European Health Union: Reinforcing the EU's resilience for cross-border health threats" (European Commission 2020). The document proposed four key initiatives aimed at strengthening the mandate of the ECDC, extending the role of the EMA, establishing a new Health Emergency

**Table 1** Legislative initiatives on the European Health Union

| | Proposal |
|---|---|
| EMA | Regulation (EU) 2022/123 of the European Parliament and of the Council of 25 January 2022 reinforcing the role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices |
| ECDC | Regulation (EU) 2022/2370 of the European Parliament and of the Council of 23 November 2022 amending Regulation (EC) No 851/2004 establishing a European Centre for disease prevention and control |
| HERA | Commission Decision of 16.9.2021 establishing the Health Emergency Preparedness and Response Authority, C(2021)6772<br>General Secretariat of the Council—Council Regulation on the emergency framework regarding medical countermeasures in the event of a public health emergency at Union level, 15132/21 |
| SCBTH Regulation | Regulation (EU) 2022/2371 of the European Parliament and of the Council on serious cross-border threats to health and repealing Decision No 1082/2013/EU |

Preparedness and Response Authority (HERA), and upgrading Decision 1082/2013/EU on serious cross-border threats to health (SCBTH Regulation for short) (table 1). Other initiatives, such as the Pharmaceutical Strategy, Europe's Beating Cancer Plan, European Health Data Space, and the EU4Health Programme, were also part of the EHU package.

## The Insititutional Design of the EHU

The institutional design of the EHU is complex. There are three key institutions: EMA, ECDC and HERA. The first two are independent agencies, the third one is a service of the European Commission. The complexity derives from two factors: on the one hand, a partial inter-institutional overlap among the various participating institutions; on the other hand, the different modes of functioning which apply in ordinary versus emergency situations. In this section, we first introduce the difference between the ordinary and emergency modes of functioning, we then illustrate the authority profile of each institution along the four aspects of our analytical grid: scope, infrastructure, participation rights, and constriction.

### Public Health Emergencies in the EU

The public health emergency regime of the EU was codified by the 2013 Decision, which enhanced the power of the inter-ministerial Health Security Committee and

entrusted the Commission with the task of declaring "public health emergencies at Union level," following WHO recommendations. The revision of this Decision and its upgrade to a Regulation as part of the EHU package has confirmed the competence of the Commission to declare public health emergencies "at Union level." This capacity stands at the core of state sovereignty since it enables the suspension of fundamental rights and the imposition of extraordinary obligations on citizens. In the new proposed framework however, the declaration of emergency needs to be based on the advice of an Advisory Committee, comprising independent experts selected by the Commission, and subsequently, needs to be approved by the "Committee on cross-border threats to health," comprising representatives of all Member States. Nevertheless, on duly justified grounds of urgency, the Commission may recognize a public health emergency at the Union level through an immediately applicable implementing act (Article 23(4) of the SCBTH Regulation). Furthermore, the Regulation expands the legal effects of emergency declarations, mainly by enabling the activation of the crisis modes of the ECDC, EMA, and HERA explained in the next sub-sections. The EHU authority pattern as regards a crucial element of public health policy—emergency declarations—is thus polyarchic, as the Commission must pass the "comitology" filter.

## Reforming EMA and ECDC

The main objective of the new Regulation concerning the EMA's mandate was to create a framework to address the issue of shortages of medicinal products and medical devices in the event of public health emergencies. In practice, the Regulation codifies the ad hoc procedures and instruments deployed in the early phase of COVID-19. EMA expanded its core activities by setting up, in March 2020, the COVID-19 EMA Pandemic Task Force (composed of senior EMA staff) and instituting other emergency procedures, such as arrangements between the agency, the Commission, manufacturers and marketing authorization holders, on the one side, and the Member States, on the other, to make available medical products to treat COVID-19.

As regards the ECDC, the new Regulation expands the agency's scope of competences, transforming its mandate from a restricted risk assessment function to direct involvement in the coordination of risk management (Deruelle and Engeli 2021). Until 2020, the ECDC had been mainly a hub for information exchange, tasked with data collection, assessment, and dissemination, as well as the provision of scientific and technical assistance to both the Commission and Member States. During the COVID-19 crisis, therefore, the ECDC's main task was to periodically release "risk assessments" and provide scientific advice on potential policy responses, with no authority in relation to prescribing appropriate actions. The amending Regulation substantially expands the mandate of the ECDC with

additional responsibilities: operational support to epidemic responses in Member States; monitoring the capacity of national health systems to respond to communicable disease threats; providing, upon request of the Commission or the HSC, public communication on health threats; providing, upon request of the Commission or the HSC, or on its own initiative, non-binding recommendations to the HSC for management of communicable diseases; and supporting the Member States and third countries in developing prevention and response against future epidemics.

The Regulation empowering EMA created new structures that are activated following the declaration of a "public health emergency" by the Commission. These include two steering groups for monitoring shortages, one on medicines and one on medical devices. Both are composed of a representative of EMA, a representative of the Commission and one representative appointed by each Member State. On their initiative or at the request of the Commission or a Member State, the steering groups may provide recommendations on measures to ensure preparedness with binding effect on the Commission, which shall take all necessary actions to mitigate product shortages. Additionally, the Member States are required to gather information on the availability of such products and submit this to the steering groups. The Emergency Task Force (ETF), modelled on the EMA Pandemic Task Force described above, is another new EMA body, to be convened in preparation for and during public health emergencies, responsible for accelerating the development and authorization of medicinal products with the potential to address public health emergencies.

As for epidemiological surveillance, the declaration of a public health emergency activates support from the ECDC, enabling it to deploy outbreak assistance teams. These teams are managed by the "EU Health Task Force"—another newly created body which increases the operational capacity of the ECDC. The Health Task Force will be integrated by ECDC staff and experts from the Member States, and its task will be to support countries with preparedness plans and swiftly intervene in health crises.

Otherwise, the two Regulations left EMA's and the ECDC's pre-existing authority structures intact. Both agencies are directed by executive structures that operate under the close strategic guidance of Management Boards while also acting as coordination hubs of networks of national experts. The Management Boards are composed of one member designated by each Member State, and other members designated by the EP and the Commission (in the ECDC case also four representatives from professional associations). The ECDC and EMA's management boards adopt their decisions by simple majority. Member States' participation in ECDC and EMA occurs not only at the executive level, but also at the administrative level, through the networks of expert committees and working groups that provide information and expertise to the agencies and contribute

to their regulatory activity. In EMA's case, this system of bottom-up national input is known as the "European medicines regulatory network." EMA has four committees, which are composed of one member representing each Member State and which rely on working parties and scientific advisory groups, which also comprise "national experts" nominated by the Member States. The regulatory network also includes the European Commission, whose principal role in the European system is to take binding decisions based on the scientific recommendations delivered by EMA. The organizational structure of the ECDC is similar: the Centre coordinates the operations of dedicated surveillance networks of national authorities, and of national reference laboratories, that assist in responses to health threats, such as field investigations in the event of disease outbreaks. What emerges from the analysis of the reforms is, again, the intertwining of national and EU actors and institutions in the governance of EMA and the ECDC.

EMA has exclusive competence in marketing authorization of medicines and medical devices, that is, constituent units cannot approve products that the agency has not approved. Additionally, EMA can monitor and advise the Member States and companies, however, it is the national authorities that carry out inspections. The new EHU rules enhance the EMA's monitoring capacity in emergencies, by establishing a system of tracking shortages of medicinal products that should prevent the lack of communication and data-sharing procedures that undermined the EU's initial response to COVID-19. In the field of epidemiological surveillance, the new regulation strengthens the constriction capacities of the ECDC, for example, by conferring to the agency the ability to provide (non-binding) recommendations.

### HERA: Ensuring the Supply of Medical Countermeasures

The EHU initiative established a third entity, the HERA, tasked with coordinating the provision of medical countermeasures. HERA constitutes an internal Commission service located within the Directorate-General for Health and Food Safety (DG SANTE), and therefore it is not an independent EU agency as was originally proposed by the Commission (see below).

HERA's activities follow two logics, corresponding to a preparedness and crisis phase. In the preparedness phase, HERA's scope is focused on knowledge production and assessment activities, such as supporting research on emerging pathogens, developing relevant countermeasures and technologies, and supporting large-scale production facilities.

In crisis phase, HERA assumes crisis management tasks. The council activates HERA's emergency framework following the recognition of a "public health emergency at the Union level" by the Commission. In this operational mode, the new framework introduces the possibility of centralized, EU-level procurement,

purchase and manufacturing of crisis-relevant medical countermeasures and raw materials. As noted, the possibility of using JPAs already existed prior to the pandemic (European Union 2013). However, the JPA had been designed as a preparedness rather than as a crisis-response instrument: its lengthy procedures did not allow for negotiating and purchasing supplies with the flexibility and speed required in extreme urgencies. Moreover, the EU's emergency support rules did not allow the Commission to purchase medical countermeasures. In April 2020, these rules were amended to allow the Commission to negotiate contracts on behalf of the Member States for the first time (Council of the EU 2020a). On this basis, the Commission was able to develop the COVID-19 vaccine strategy. This framework implied an agreement signed by the Commission and the Member States that made the Commission responsible for the procurement process and the conclusion of contracts.

In the case of the COVID-19 vaccines, the agreement set up a monitoring system centered upon two bodies: a Steering Board overseeing negotiations and validating contracts before signatures, composed of one representative per Member State and co-chaired by the Commission and a Member State representative; and a "joint negotiation team" in charge of negotiating contracts, made up of Commission officials and representatives from seven Member States (France, Italy, Germany, the Netherlands, Poland and Sweden) out of the twenty-seven participating countries.

The HERA regulation institutionalized the experience of COVID-19 management in joint EU procurement. Article 7 enables the Commission to act as a "central purchasing body" for crisis-relevant countermeasures on behalf of Member States that wish to participate in joint procurement. Although the Commission carries out and concludes the negotiations with economic operators on behalf of the participating Member States, Member States participating in the Health Crisis Board can nominate representatives "to take part in … the negotiations." Furthermore, the deployment and use of crisis-relevant medical countermeasures remain the responsibility of the participating Member States.

HERA's management changes depending on the preparedness and crisis modes. In the preparedness mode, HERA's organizational structure resembles the EMA and the ECDC. It is governed by the Head of HERA, appointed by the Commission. The Head of HERA is "assisted" by the HERA Board, which is composed of one representative from each Member State, in the formulation of strategic decisions. When HERA's emergency framework is activated, another ad hoc crisis entity, the Health Crisis Board, assumes the tasks of the HERA Board. It is composed of one Commission representative and one representative from each Member State but is chaired by the Commission and has a Secretariat composed of Commission officials.

## Cross-Border Threats to Health: From Knowledge Production to Crisis Management

The fourth initiative included in the EHU agenda is the new Regulation on Serious Cross-Border Threats to Health amending the 2013 Decision on the same issue. This initiative has a transversal character because it redesigns the EU's public health security framework, and therefore, the links between all the bodies and instruments examined so far. Its main purpose is to shift some crisis management functions to the EU level.

Regarding knowledge production and circulation, the legal framework for epidemiological surveillance and response to cross-border threats is broadened to include additional reporting requirements and analysis on health systems indicators, and cooperation by Member States with the ECDC. The Regulation redefines the so-called "epidemiological surveillance network," reinforcing the role of the ECDC within it. The aim of this network is to ensure permanent communication between the Commission, the ECDC, and the competent authorities at the national level. A novelty introduced by the reform is the joint definition, by the Commission and the Member States, of common European surveillance standards, adherence to which is monitored by the ECDC, reporting to the HSC its assessments. The ECDC's interactions with the EU Member States happen (also) through the newly established EU reference laboratory network. Therefore, the EU-level infrastructural power is expanded, but participation rights are guaranteed for national actors, that is, representatives of national public health institutes that undertake tasks like those of the ECDC at the national level.

The Regulation also expands the scope of the Health Security Committee (HSC). Chaired by a representative of the European Commission and comprising representatives of the Member States, the HSC can adopt its recommendations by a two-thirds majority of the members. The HSC is endowed with the task of coordinating, in liaison with the Commission, the preparedness and crisis response planning of Member States for cross-border health emergencies. In fact, a "Union health crisis and pandemic preparedness plan" needs to be established by the Commission and approved by the HSC. But the HSC acquires new tasks not only in relation to prevention but also in relation to crisis management. Following an alert notification from the Commission or a Member State, crisis management moves to the HSC, where the Commission and the Member States coordinate national responses, issue joint crisis communications, and adopt guidance on specific crisis responses of the Member States. Should the coordination of national public health measures prove insufficient to ensure an adequate Union response, the Commission provides further support to the Member States via the adoption of recommendations on temporary public health measures. The constrictive capacity of the responsible bodies remains low, but the introduction of soft law instruments provides them, nonetheless, with minimal tools for eliciting compliance.

## Joint Authority at the Centre

### The EHU's Distinctiveness

As our empirical reconstruction demonstrates, the key scope extension of the EHU package (that is, a new domain of legitimate EU intervention) has been the shift from risk assessment to crisis management (table 2). Central to this is the Commission's ability to declare a public health emergency "at Union level," and the expansion of the legal effects that this declaration entails. At the same time, preexisting capacities have also been strengthened, especially as regards surveillance of Member States, which has been made stronger and wider (though with important caveats, as we explain below). Nonetheless, scope extensions were combined with a complex system of participation rights reserved for the Member States in newly created and preexisting bodies, ensuring shared decision-making "all the way up."

The three main EHU bodies (EMA, ECDC, and HERA) make up the core of the EHU, while a plethora of other infrastructures populate the institutional space. These bodies are the ones inserting the "expansive unification" logic in the EU public health architecture. There is the Health Security Committee, comprising representatives of the Member States and the Commission: a hybrid body acting in the executive arena. The "Committee on cross-border threats to health" is active in the administrative sphere: it includes representatives of the Member States who must give the green light to the implementing acts of the Commission in an emergency. The managing Boards of all bodies have a mixed composition, including representatives of the Member States, the Commission, and, in the case of the Health Security Committee, a representative appointed by the European Parliament as an observer. The EP can request the ECDC's scientific opinion on matters falling within its mission, while the EMA shall present a report on crisis preparedness (foreseen in 2026) to the European Parliament (and the Council). Note that the direct inclusion of MEPs in federal-level executive and administrative decisions is a peculiar feature of the EHU. In case of emergency, the HERA Health Crisis Board takes charge, activating the emergency bodies of the ECDC and EMA: the EU Health Task Force, the Emergency Task Force, the steering groups of the European Medicine Regulatory Framework and the Coordination Committee. Decentralized institutions (focal points, reference labs) which liaise the ECDC with the Member States complete the institutional setup.

The EHU is also equilibrated in terms of the degree of constriction, that is, the extent to which decisions are binding. While the EU's power to enforce a coordinated response has been incrementally expanded, nonetheless Member States have retained their prerogatives in important ways. This has happened not only through their representation in new and old bodies and committees (sharing *in* rule), but also because of the low prescriptiveness of any decisions taken. For

**Table 2** Expansive unification: authority reconfiguration through the EHU

| Authority dimensions | EHU innovations |
|---|---|
| Expansions in scope | ECDC increases its role in crisis management in addition to risk management:<br>• advise Member States and the Commission about preparedness plans<br>• new right to activate EU Health Task Force<br>• right to issue non-binding recommendations for risk management<br>• new right to define a framework for reporting and auditing<br><br>EMA co-monitors potential shortages of medical countermeasures<br>Member States can mandate Commission for joint procurement in emergency situations |
| New infrastructures | Increased power to enforce a coordinated response through the HSC<br>Strengthened, integrated surveillance systems<br>EMA's emergency task force<br>EMA's medicines and medical devices steering groups<br>EU health task force<br>Health task force has the duty to prepare an EU health crisis and pandemic preparedness plan<br>Institutionalization of HERA's health crisis board to manage HERA in emergency situations<br>Advisory Committee on public health emergencies |
| New rights of participation | Member States involved in the decision-making of pre-existing and new bodies<br>Member States obtain co-chairmanship of the HSC<br>The European Parliament can participate in the HSC as observer |
| New tasks backed by constriction | Declaring public health emergencies at Union level<br>Stronger Member State surveillance on the side of the Commission<br>New reporting obligations for the Member States as well as private companies |

instance, with regards to the joint procurement procedure, while the Commission negotiates, Member States retain a final say; likewise, while Member States assume the obligation to prepare national pandemic preparedness plans, the ECDC's ability to scrutinize these plans is limited, and it can only issue recommendations—and so forth.

Overall, then, the distinctive feature of the EHU lies precisely in the high degree of "fusion" between the central level and the Member State levels. The supranational body *par excellence*, that is, the Commission, exercises its executive

and administrative powers under close control and often in conjunction with the Member States *uti singuli*, that is, without the filter of the Council and its system of weighted votes (whereby the number of votes varies according to population size). In this sense, the EHU is a marble cake "all the way up": national governments sit in the powerful Council as well as in the executive and the administrative arenas, casting the shadow of potential vetoes on the overall decision-making process. It would be misleading, however, to downplay the power of the Commission, as the latter wields an autonomous source of authority: its Treaty-based monopoly of legislative proposal, which casts the shadow of a counter-hierarchy vis-à-vis the comitology system. This prerogative enhances the Commission's autonomy, as it can in principle shift a controversial issue from the administrative to the legislative arenas, where different voting rules apply. It is true that, empirically, neither vetoes nor strategic shifts have taken place (at least so far). But the mere existence of such possibilities structures the incentives and opportunities of power interactions, through the mechanism of anticipated reactions.

## How Did we Get Here: Expansive Unification through Constructive Conflict

What kind of political dynamics enabled EHU-building and what can this tell us more broadly about the process of expansive unification? Owing in part to the emergency and in part to the Commission's design of the proposals to codify already practised ad hoc measures rather than introduce radical changes, the crisscrossing territorial and partisan conflicts that usually characterize EU social politics (Ferrera 2017) were largely absent on this occasion. The main line of disagreement arose between the Council of the EU and the EP, each of them following a distinct institutional logic.

On the one hand, Member State ministers, while acknowledging the need for more public health centralization, pursued a deliberate strategy for maintaining or asserting (joint) control over the newly established or reinforced bodies, guaranteeing their involvement in any key decisions (Cox and Kurzer 2024). As can be gleaned through the mandates and other Council documents (e.g., Council of the EU 2020b; Council of the EU 2021a, 2021b; see also: *Politico* 2021), during their deliberations and the interinstitutional negotiations that followed the Commission's proposals, the Council of ministers demanded co-chairmanship in the newly created structures, where this was not already granted. They also consistently inserted clarifications and caveats into the Commission's original proposals, changing the language of the texts to insist on their nonbinding character. They sought to limit the extensive surveillance regime initially proposed by the Commission, by for example, demanding longer review cycles; and generally argued for more Member State autonomy. Overall, while acknowledging the functional need to coordinate at the center, the Member States were reluctant to

relinquish control, thus they mobilized to preserve their role as ultimate decision makers.

On the other hand, the EP not only supported the expansion of central powers as proposed by the Commission, but also on occasion advocated for expanding them even more. For example, the EP sought to increase accountability of the Member States where they had resisted it, for example, by proposing that both the Commission and the Member States should be required to provide "substantiated justification" if recommendations made by an EMA steering group are not considered. Similarly, regarding the ECDC's mandate, inter alia, to assess the Member States' preparedness and response planning or the obligation for Member States to notify reporting delays, the EP preferred a supervisory rather than simply a supporting role. The EP called for the new powers (in both their scope and infrastructural dimensions) to apply also beyond crisis-situations (in the case of EMA) and to cover non-communicable diseases (in the case of the ECDC). These proposals did not make it into the final texts, marking the limits of authority transfer to the center in the expansive unification pattern.

In the case of HERA, the policymaking process took a different route. It was somewhat more conflictual, and it involved horizontal inter-state tensions. The Commission presented five possible ways to implement HERA (European Commission 2021: 3–4) starting from the least ambitious (status quo or marginally strengthened cooperation) to the most ambitious option (full end-to-end authority). Member States were divided on the new responsibilities attributed to HERA: some governments (such as Spain, Belgium, the Netherlands) agreed with the Commission's diagnosis and converged towards a rather expansive version (EPRS 2021: 5), while others (Romania, the Czech Republic, or Denmark) stressed the importance of respecting the division of competences between EU institutions and Member States. Governments were also cool to the prospect of the Commission auditing their health systems to determine their pandemic preparedness (EPRS 2021: 6). Given this disagreement and working under time pressure, HERA was eventually set up as an internal department within the Commission (a "Commission service") via a Decision on 16 September 2021. Because of the chosen legal basis (Article 122), while an accompanying Council regulation was necessary to approve it, the EP was excluded from the policymaking process, though MEPs were still granted an observer role on HERA's board and a vote on the budget.

Overall, the dynamics behind the establishment of the EHU can be largely accounted for based on a combination of neofunctionalist and new intergovernmentalist logics: while the increasing costs of cross-border spillovers made room for empowering both the Commission and interest groups to push for EU-wide solutions, the authority did not shift to the Commission directly, but mostly to semi-independent agencies and bodies whose institutional design is more

hospitable to the influence of Member States. However, mainstream integration theories perform better in illuminating the drivers of integration rather than the workings of the EU. And this is also the case for the EHU, whose functioning cannot be captured by the supranational–intergovernmental dichotomy. Thus, while new intergovernmentalist theory holds that these semi-independent bodies become increasingly important in the post-Maastricht period at the expense of supranational institutions (Bickerton, Hodson, and Puetter 2015), the literature on EU agencies sustains the opposite: "even if national delegates may dominate numerically on the management boards of EU agencies . . . they may in practice be loosely coupled to ministers,", these bodies "tending to lean more towards the Commission than any other potential masters" (Egeberg and Trondal 2017: 679).

Our concept of expansive unification accounts for this apparent paradox: rather than institutional rivalries and inter-institutional zero-sum games, what the design of the EHU shows are horizontal dynamics featuring multiple checks and balances and a polyarchic exercise of joint authority at the center between the Commission, Member States representatives, and health agencies. Positive-sum authority expansion facilitated the building of the EHU, by containing both vertical tensions (between the center and the constituent units) and horizontal tensions (between the legislative triangle at the top; between constituent units at the bottom).

## Mobilizing Consensus in the Pandemic: Downstream Implications of the EHU

The literature broadly agrees that the EU management of the COVID-19 pandemic, at least in health policy terms, was rather satisfactory (Dimitrakopoulos and Lalis 2022; Rhodes 2021; Brooks et al. 2023). This positive judgment can be reinforced if one considers that during the crisis the Union engaged with a double and demanding task: that of immediately responding to the pandemic emergency through regulatory and partly spending policies while at the same time launching a constituent process, that is, designing and legislating the institutional architecture of a novel permanent structure such as the EHU. This represented a rare and successful example of "building the ship while sailing": in fact, the EHU package has mostly codified and systematized the ad hoc measures taken during the various phases of the pandemic.

After a period of internal discord during the first weeks of the pandemic in Europe, the EU proceeded to make the most of its limited competences (Rhodes 2021), its functional performance visibly increasing over time. Already in early March 2020, the Commission activated the Health Security Committee and created a new panel of epidemiologists and virologists to advise it; it also activated and subsequently expanded the "rescEU" stockpile of supplies also increasing its budget. The Commission was endowed with the task of joint medical supply procurement, which, between 2020 and 2021, aside from the vaccination campaign,

produced four joint procurements of personal protective equipment. The authorization and supply of vaccines faced some setbacks early on but were overall successful (Martinsen and Goetz 2022, 3). Other EU actions included coordination of the redistribution of health professionals and patients across Member States, helping to overcome medical supply problems, and successfully coordinating the lifting of mobility restrictions during 2020 (Brooks et al. 2023).

Research on the United States and Switzerland—the most emblematic cases of "coming together federations" (Stepan 1999) and thus most comparable to the EU—has pointed out, instead, several handicaps in the management of the pandemic resulting from the compound nature of their political systems, resting on a double (horizontal and vertical) division of power. In the US, public health responses have been negatively affected by lack of established infrastructures of coordination and cooperation across levels of government, as well as by multi-level partisan rivalries and the dominance of political interests (Alexander Shaw, Ganderson, and Schelkle 2022). In Switzerland, the federal center initially took over—possibly overstepping its constitutional limits—stripping the cantons of their co-decision prerogatives and relegating them to the role of mere implementers. This produced a subsequent backlash which blurred both accountability and effectiveness (Uhlmann and Ammann 2021).

In contrast, despite its weak constriction capacities, the EU mobilized a surprising degree of consensus in its crisis management. Of course, part of the explanation lies in the relatively limited competences of the EU, implying fewer incentives for public attention and politicization. At the same time, it can be argued that the "expansive unification" mode of integration significantly facilitates conflict resolution and inter-institutional cooperation at both the vertical and the horizontal levels. As argued by the literature on federalism, strong vertical coordination fosters trust enables the convergence of interests and enhances the reliability of inter-governmental interactions (Schnabel and Hegele 2021). The authority patterns which we have dubbed "marble cake all the way up" can be seen as an extreme case of vertical coordination in which the constituent units jointly exercise federal powers at the center. The absence of multi-level partisan rivalries has neutralized the conflict dynamics which plagued the US experience. The balance of power between the Member States (acting at the center) and the Commission in the executive and administrative arenas has in its turn contained the political strains inherent in the double separation of powers (vertical and horizontal) which characterizes compound polities (Fabbrini 2007).

## Conclusion

The EHU exemplifies a mode of integration that we have called expansive unification. In the field of public health, this mode of integration has opened the

functional boundaries of the Member States, but it has not weakened their political role. The EHU has not inaugurated a top-down infiltration on the side of a supranational center of a previously autonomous policy space of domestic polities. Quite to the contrary, it has promoted upward enablement of national governments in steering new common policies at the center.

The EHU rests on governance structures that are neither intergovernmental nor supranational since decision-making powers are exercised together by supranational institutions and the Member States. Both the national executives and the Commission retain (and have gained, in fact) important prerogatives in all EU-level ambits of authority and decision-making arenas. Even the European Parliament has acquired the unprecedented right of a "jump seat" in the management of the Health and Security Committee. Thus, expansive unification displays features that cut across the intergovernmental–supranational divide.

Our account offers further evidence that a "weak center"—essentially based on the "sharing *in* rule" principle—constitutes a distinctive feature of the EU as a compound polity of nation-states (Alexander Shaw, Ganderson, and Schelkle 2022). The center is not an autonomous and separate layer of binding authority. EHU-building has instead created a composite and polyarchic center: less an autonomous source of top-down ultimate authority than a site for the joint exercises of authority. In a way, the center is itself a marble cake, in which the supranational and the national levels/authorities intermesh with each other in both functional and institutional terms. If the essential feature of federalism is less the presence of policy co-determination than the independence of both the central authority and the authorities of the constituent units, then the EHU (and more generally expansive unification) does not bring the EU closer to the federal template. However, the deep formalized enmeshment of domestic and supranational institutions in the making of constrictive decisions sets the EHU apart from the confederal template, as typically exemplified by the World Health Organization.

To what extent does the logic of expansive unification inform also other recent advances in the integration of other core state powers in the EU? There are signs that such logic has indeed driven developments in other domains, such as electricity regulation (Rangoni 2023), the functioning of the European Asylum Support Office in asylum policy, or the design of the Single Supervisory Mechanism for Banking Union. Also, in these cases, to strike a balance between joint EU action, national diversity and technical expertise, new governance architectures have been established, and managed at the EU level through the interaction between the Commission, national officers and independent experts (Rangoni 2023). These types of unification also depart from the EU's classical "regulatory polity" (Majone 1994) approach because they entail an expansion of supranational capacity building (e.g. staff and funds).

The expansive unification logic may indeed become increasingly present in other sectors of EU integration subject to both functional pressures for centralization and sovereignty concerns among the Member States. Indeed, our analysis of the public health domain supports the view that the Member States can accept building new authority structures at the center as long as they retain channels of participation within them, including at the administrative stage. These mechanisms of joint authority are important in the EU compound polity to the extent that they foster shared understanding, give rise to stabilizing polity norms (Pettit 2023), and mitigate conflict across jurisdictional frontiers.

## Notes

Our research was supported by the European Research Council under the Synergy Grant number ERC_SYG_2018 grant number 810356, for the project Policy Crisis and Crisis Politics. Sovereignty, Solidarity and Identity in the EU post 2008—SOLID.

## References

Alexander Shaw, Kate, Joseph Ganderson, and Waltraud Schelkle. 2022. The strength of a weak centre: Pandemic politics in the European Union and the United States. *Comparative European Politics* 21: 448–479.

Anderson, Michael, Rebecca Forman, and Elias Mossialos. 2021. Navigating the role of the EU Health Emergency Preparedness and Response Authority (HERA) in Europe and beyond. *The Lancet Regional Health—Europe* 9.

Barnes Barry. 1988. *The nature of power*. Illinois: University of Illinois Press.

Bartolini, Stefano. 2022. *Rule-making rules: An analytical framework for political institutions*. Cambridge: Cambridge University Press.

Beaussier, Anne-Laure, and Lydie Cabane. 2020. Strengthening the EU's response capacity to health emergencies: Insights from EU crisis management mechanisms. *European Journal of Risk and Regulation* 11 (4): 808–820.

Benson, David, and Andrew Jordan. 2008. Understanding task allocation in the European Union: Exploring the value of federal theory. *Journal of European Public Policy* 15 (1): 78–97.

———. 2011. Exploring the tool-kit of European integration theory: What role for cooperative federalism? *Journal of European Integration* 33 (1): 1–17.

Bickerton, Chris J., Dermot Hodson, and Uwe Puetter. 2015. The new intergovernmentalism: European integration in the post-Maastricht era. *Journal of Common Market Studies* 53 (4): 703–722.

Boin, Arjen, and Mark Rhinard. 2023. Crisis management performance and the European Union: The case of COVID-19. *Journal of European Public Policy* 30 (4): 655–675.

Brooks, Eleanor, Anniek de Ruijter, Scott L. Greer, and Sarah Rozenblum. 2023. EU health policy in the aftermath of COVID-19: Neofunctionalism and crisis-driven integration. *Journal of European Public Policy* 30 (4): 721–739.

Caputi, Mary, 2013. *Feminism and power: The need for critical theory*. Lanham, MD: Lexington Books.

Cigler, Beverly A. 2021. Fighting Covid-19 in the United States with federalism and other constitutional and statutory authority. *Publius* 51 (4): 673–692.

Council of the EU. 2020a. Regulation (EU) 2020/521 of 14 April 2020 activating the emergency support under Regulation (EU) 2016/369, and amending its provisions taking into account the COVID-19 outbreak. *Official Journal of the European Union* 117/3.

———. 2020b. Proposal for a Regulation of the European Parliament and of the Council on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices—General approach (adopted on 15 June 2021).

———. 2021a. Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 851/2004 establishing a European Centre for disease prevention and control—Mandate for negotiation with the European Parliament.

———. 2021b. Proposal for a Regulation of the European Parliament and of the Council on serious cross-border threats to health and repealing Decision No 1082/2013/EU—Mandate for negotiation with the European Parliament.

Cox, Robert Henry, and Paulette Kurzer. 2024. For want of a champion: Why the EU won't be ready for the next public health crisis. *Journal of European Public Policy* 31 (2): 610–631.

Deruelle, Thibaud, and Isabelle Engeli. 2021. The COVID-19 crisis and the rise of the European Centre for Disease Prevention and Control (ECDC). *West European Politics* 44 (5–6): 1376–1400.

Dimitrakopoulos, Dionyssis G., and Georgette Lalis. 2022. The EU's initial response to the COVID-19 pandemic: Disintegration or 'failing forward'? *Journal of European Public Policy* 29 (9): 1395–1413.

Egeberg, Morten, and Jarle Trondal. 2017. Researching European Union agencies: What we have learnt (and where do we go from here.)? *Journal of Common Market Studies* 55 (4): 675–690.

EU4Health. 2020. COVID-19 has shown EU action on health is more urgently needed than ever. Available at: https://eu4health.eu/covid-19-has-shown-eu-action-on-health-is-more-urgently-needed-than-ever/

European Commission. 2020. Building a European Health Union: Reinforcing the EU's resilience for cross-border health threats. COM(2020)74 final, Brussels, November 11.

———. 2021. Proposal for a Regulation of the European Parliament and of the council establishing a European Health Emergency Response Authority (HERA). Document Ares (2021)674649 (Inception impact assessment).

European Ombudsman. 2021. Executive summary of strategic inquiry OI/3/2020/TE into how the ECDC performed during the COVID-19 crisis.

European Parliament. 2020. European Parliament resolution of 10 July 2020 on the EU's public health strategy post-COVID-19.

EPRS. 2021. European Health Emergency Preparedness and Response Authority (HERA) Pre-legislative synthesis of national, regional and local positions on the European Commission's initiative.

European Patients Forum. 2020. High time for enhanced European coordination and competence on health.

European Public Health Alliance. 2020. COVID-19 reveals urgent need for a common European public health approach.

European Union. 2013. Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October on serious cross-border threats to health and repealing decision No 2019/98/EC. Official Journal of the European Union, 293/1.

Fabbrini, Sergio. 2007. *Compound Democracies: Why the United States and Europe are Becoming Similar*. Oxford: Oxford University Press.

———. 2017. Which democracy for a union of states? A comparative perspective of the European Union. *Global Policy* 8(S6): 14–22.

Fenna, Alan, and Johanna Schnabel. 2023. What is Federalism? Some Definitional Clarification. *Publius*, online first.

Ferrera, Maurizio. 2017. The Stein Rokkan lecture 2016 mission impossible? Reconciling economic and social Europe after the euro crisis and Brexit. *European Journal of Political Research* 56 (1): 3–22.

Ferrera, Maurizio, Hanspeter Kriesi, and Waltraud Schelkle. 2024. Maintaining the EU's compound polity during the long crisis decade. *Journal of European Public Policy* 31 (3): 706–728.

Fierlbeck, Katherine, and Howard A. Palley, eds. 2015. *Comparative Health Care Federalism*. London: Routledge.

Forman, Rebecca, and Elias Mossialos. 2021. The EU response to COVID-19: From reactive policies to strategic decision-making. *Journal of Common Market Studies* 59 (S1): 56–68.

Genschel, Philip, and Mark Jachtenfuchs. 2016. More integration, less federation: The European integration of core state powers. *Journal of European Public Policy* 23 (1): 42–59.

Greer, Scott L. 2021. Health, federalism and the European Union: Lessons from comparative federalism about the European Union. *Health. Economics, Policy and Law* 16 (1): 90–103.

Greer, Scott L., Anniek de Ruijter, and Eleanor Brooks. 2021. The COVID-19 pandemic: Failing forward in public health. In *The Palgrave Handbook of EU Crises*, eds. M. Riddervold, J. Trondal, and A. Newsome, 747–764. Cham: Palgave MacMillan.

Grodzins, Morton. 1966. *The American system: A new view of government in the United States*. New Brunswick, NJ: Transaction Publishers.

Kelemen, Daniel. 2013. Building the new European State? Federalism, core state powers, and European integration. In *Beyond the regulatory polity? The European integration of core state powers*, eds. P. Genschel and M. Jachtenfuchs, 211–229. Oxford: OUP.

Ladi, Stella, and Sarah Wolff. 2021. The EU institutional architecture in the Covid-19 response: Coordinative Europeanization in times of permanent emergency. *Journal of Common Market Studies* 59 (1): 32–43.

Lamping, Wolfram. 2005. European integration and health policy: A peculiar relationship. In *Health Governance in Europe: Issues, Challenges and Theories*, ed. M. Steffen, 11–48. London: Routledge.

Majone, Giandomenico. 1994. The rise of the regulatory state in Europe. *West European Politics* 17 (3): 77–101.

Mann, Michael. 1984. The autonomous power of the state: Its origins, mechanisms and results. *European Journal of Sociology* 25 (2): 185–213.

Martinsen, Dorte S., and Klaus H. Goetz. 2022. COVID-19 and European multi-level democracy. *Journal of Common Market Studies* 60: 137–149

Mueller, Sean, and Alan Fenna. 2022. Dual versus administrative federalism: Origins and evolutions of two models. *Publius* 52 (4): 525–552.

Pansardi, Pamela, and Marianna Bindi. 2021. The new concepts of power? Power-over, power-to and power-with. *Journal of Political Power* 14 (1): 51–71.

Parsons, Talcott. 1963. On the concept of political power. *Proceedings of the American Philosophical Society* 107 (3): 232–262.

Pettit, Philip. 2023. *The state. On the nature and norms of the modern polity*. Princeton: Princeton University Press.

Politico. 2020. National capitals question EU's pandemic preparedness. June 10.

———. 2021. HERA isn't the hero Parliament wants—or the game-changer Council fears. September 17.

Rangoni, Bernardo. 2023. *Experimentalist governance: From architectures to outcomes*. Oxford: Oxford University Press.

Read, James. 2012. Is power zero-sum or variable-sum? Old arguments and new beginnings. *Journal of Political Power* 5 (1): 5–31.

Rhodes, Martin. 2021. "Failing forward": A critique in light of covid-19. *Journal of European Public Policy* 28 (10): 1537–1554.

Schnabel, Johanna, and Yvonne Hegele. 2021. Explaining intergovernmental coordination during the COVID19 pandemic: Responses in Australia, Canada, Germany and Switzerland. *Publius* 51 (4): 537–569.

Scholz, Nicole. 2021. Cross-border health threats. EU action on preparedness and response. PE690.565, European Parliamentary Research Service.

Stepan, Alfred. 1999. Federalism and democracy: Beyond the U.S. model. *Journal of Democracy* 10 (4): 19–34.

Türk, Alexander. 2015. "Comitology". In *The Oxford Handbook of European Union Law*, ed. Damian Chalmers and Anthony Arnull, 327–349. Oxford: Oxford University Press.

Uhlmann, Felix, and Odile Ammann. 2021. Switzerland and the COVID-19 pandemic: A look back and a look into the future. *Verfassungsblog*, March 1.

Vollaard, Hans, Hester Van de Bovenkamp, and Dorte S. Martinsen. 2016. The making of a European healthcare union: A federalist perspective. *Journal of European Public Policy* 23 (2): 157–176.

Vollaard, Hans, and Dorte S. Martinsen. 2017. The rise of a European healthcare union. *Comparative European Politics* 15 (3): 337–351.

Zalc, Julien, and Robin Maillard. 2020. Uncertainty/EU/hope: Public opinion in times of Covid-19. Public Opinion Survey Commissioned by the European Parliament.

Zürn, Michael, Alexandro Tokhi, and Martin Binder. 2021. The international authority database. *Global Policy* 12 (4): 430–442.