EU Decision-Making During a Crisis: Public Health Initiatives

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Abstract:

This article argues that the EU response to the COVID-19 crisis follows a pattern much like its response to earlier public health threats. Though each time the EU commits to being prepared for the next health crisis, as the immediate crisis recedes, so does the momentum to build the necessary administrative capacity, leaving the EU unprepared to take a leadership role when the next public health crisis emerges. An examination of the modest efforts to build administrative capacity after several recent public health crises (SARS, Avian Flu, MERS and COVID-19) show that supranational integration does not happen without sustained attention and political determination or sacrifices after the crisis. Despite the claims that COVID-19 was a new level of public health crisis that demanded supranational action, the EU response seems to fall back into a familiar pattern of minor tweaks.

COVID-19 must be counted as one of the worst crises the EU (and the world) has faced during the last decades. Our article asks whether this crisis will result in a stronger EU health presence, especially in the field of communicable diseases?[1] Or will we see more of the same in that public health is subordinate to the single market and market integration? There are theoretical reasons to expect that the EU will muddle through and address the most urgent elements of the crisis without investing in new institutions and programs. This prediction is based on the way in which human health is currently handled at the European level which is mostly an extension of economic freedoms and market efficiency (Greer & Jarman 2021). This expected outcome also reflects the political reality of the Council where consensus is harder to forge in controversial policy domains like public health. Indeed, public health in particular represents a notable phase of the historical cultural evolution of a country. Public health with its focus on sanitation and disease surveillance evolved different political and administrative structures across Europe (Mätzke 2012). This complicates the mission of the Commission to go beyond disease

[1] We only examine public health, which is population focused and based on public law, versus health or health care which is patient/individual focused and based on private law.

monitoring and risk assessment and formulate more comprehensive and coherent initiatives in public health.

However, there is also reason to believe that EU disease control and public health may in fact become more substantial, with more autonomy and funding once the pandemic is over. This alternative view is supported by the events triggered by another crisis: the Eurozone crisis. For example, the Eurozone moved from a total rejection of bailouts and grants to a conditional acceptance ten years later. With the pandemic, European countries were caught flat footed and lacked basic preparedness to cope with a contagious virus, something that most political leaders will want to avoid in the future. The transboundary nature of epidemics brings home that it might make sense to transfer some policy authority with respect to public health to the EU and support further integration. Another reason for speculating that the EU will invest in strong public health competences is that expert agencies have gained more influence and visibility during the pandemic and the initial failings of the EU to coordinate around a coherent response to the pandemic has given rise to new initiatives.

Though a variety of future outcomes are possible, assessing recent history we assert that the most likely outcome is a reversion to the mean. Despite grand expectations that this time the EU will prepare itself for future crises in public health, we expect instead that after the immediacy of the crisis recedes, momentum to follow through will disappear, and the EU will fail to complete the necessary administrative capacity to really prepare for the next big pandemic. Our argument makes two contributions to the discussion of whether the pandemic is likely to Europeanize public health. The first contribution is a theoretical argument that seeks to more clearly specify

one condition in which a crisis could lead to no development at the European level. The condition is a lack of sustained attention to a policy area except during a crisis. This leads to a failure to imbue new initiatives with sufficient administrative capacity to carry out new tasks. The second contribution is an empirical assessment of the possibility for the pandemic to lead to a European Health Union, specifically.

Our general argument draws from the notion developed by Jones, Keleman and Meunier (2016) that the typical trend in the EU is one of "failing forward." Examining the European Monetary Union (EMU), Jones, Keleman and Meunier argue that the diverse preferences of member states during intergovernmental bargaining lead to lowest common denominator outcomes. Such outcomes have inherent flaws in that they either generate their own internal crisis, or are unworkable in the face of a crisis with an external source. To address the crisis, member states then negotiate another sub optimal reform, repeating the cycle. Over time, this cycle of piecemeal reform leads to further integration because each effort to address the failure involves a small degree of integration at the European level. The argument works in the case under examination, but it is heavily reliant on the particular scope conditions of the EMU. The authors of the study recognize this limitation (for example, Jones, Keleman and Meunier 2021) and call on others to test the argument in other policy areas. In this study we take up that challenge and apply the argument to the case of Europeanization of public health and the impact of pandemic crises on European integration.

Administrative Capacity as a Scope Condition

Other scholars have noted that the 'failing forward' thesis is heavily reliant on the scope conditions of the EMU (Rhodes 2021). Applying the argument to EU migration policy, Marco Scipioni (2018) argues that a lack of administrative capacity at the EU level leads to greater intergovernmental gridlock in that policy domain. When this administrative capacity is absent, we should expect little progress toward integration. Indeed, there is an established literature that examines the role of state capacity in a country's effectiveness in crisis management. One important point in this literature is that states with strong administrative capacity have a robust capacity in information gathering, decision-making, implementation, and cooperation, and evidence suggests that countries with strong capacity also handled the COVID crisis more effectively (Mao 2021; Wong 2020). In such states, agencies have more staff, are more likely to rehearse crisis responses and have strong networks that facilitate communication and coordination. Therefore, when a crisis erupts, these agencies are able to leap into action, rather than improvising a crisis response in the moment.

Scholars who have studied the EU's administrative capacity, note an unevenness to the character of capacity building. Philipp Genschel and Markus Jachtenfuchs (2016) observed that as more treaty agreements increase the level of European integration in a formal sense, this often comes *without* the development of the material capacity to carry out the new roles. Instead of capacity building, they demonstrate that greater integration often leads to more institutional fragmentation, increased territorial differentiation, and a heavier reliance on regulation as the primary policy tool. Thus, we might expect that in areas of low administrative capacity, such as public health, crises might not provide the opportunity to advance Europeanization. Instead, we

expect to see a new crisis produce momentum to reform, but that as the crisis abates, so does the momentum, and the necessary capacity is never adequately completed.

In what follows, we explore this argument through a historical narrative of the development of European competence in the field of public health, focusing on the impact of crises as triggers for further integrative action. Viewed up close, the overriding pattern we see is one where public health is of low salience at the European level though an epidemic occasionally triggers a crisis that temporarily raises its salience. At such times, there is wide agreement that the EU must do something because (transboundary) pandemics require collective action among states. However, again and again, the lessons learned are not acted upon and are not well integrated with previous crisis responses. We argue this is because when the urgency of the issue subsides, EU public health authorities are left with little additional administrative capacity to maintain the momentum and build out the institutional capacity.

Our argument diverges from the "failing forward" thesis in one important respect. Whereas failing forward is produced by member states who, during intergovernmental bargaining resist ceding authority to EU officials, in the area of public health a lack of sustained commitment to the issue after the crisis is an additional factor. In cases of failing forward, the suboptimal agreements struck through intergovernmental bargaining are often themselves the cause of future crises. In the case of public health, the crises are always externally generated, but the EU struggles to handle them at the supranational level.

Why 'Failure to Complete' is Common to Some Policy Areas

As is well-known, the EU's founding treaties afford it limited legislative power in the field of human health. While Article 168 of the Treaty on the Functioning of the European Union (TFEU) states that "a high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities," in reality EU health policy itself is underdeveloped. Article 168 TFEU stresses that EU institutions can consider measures to protect and improve human health, but it cannot lead to harmonization of laws and regulations, and it should respect the responsibilities of the member states in formulation, delivering health services and medical care.

It is no mystery why member states curtailed the ability of the EU to formulate EU health policies. Health spending in aging societies is one of the largest budget items and affects one way or the other every EU resident. Moreover, health spending emerged over decades of welfare state building and reflect distinctive features and priorities that are deeply embedded in the collectivist expression of the nation state.

In spite of these restrictions, the EU has become more involved in public health though its achievements are somewhat under the radar (Hervey & McHale, 2015; Greer & Kurzer, 2013). The current treaties permit the EU to harmonize national laws in a small set of specific areas, such as organs and substances of human origin, pharmaceuticals and medical devices. In all other areas of health, including crisis response management, pharmaceutical procurement and infectious disease containment, the EU's role is limited to supporting national policies and encouraging coordination (Brooks & Geyer 2020).

Looking back across the history of the EU, public health crises -- HIV/AIDS, bovine tuberculosis , bovine spongiform encephalopathy (mad cow disease 1996), SARS in 2003, influenza pandemic of 2005 and 2009 – constituted opportunities for weighing various forms of pan-European intervention and a window for improving preparedness, cooperation, and capacity. For at least two decades, the EU has been involved in communicable disease control and prevention, but its capabilities remained limited and its activities or mission was subordinate to national agencies and policies (Greer, de Ruijter & Brooks, 2021). The reason crises did not generate an expansion of EU authority in public health, we argue, is that after the crisis abates, attention moves away from a policy field where there is no constitutional basis to sustain the activity at the EU level. As a result, the administrative capacity imagined in the heat of the crisis does not get fully completed.

Crisis and Capacity-Building in EU Public Health

In the area of public health, crises compel the EU to develop a capacity to respond to the crisis it has just experienced. Though in doing so, the EU typically makes incremental adjustments (Bengtsson and Rhinard 2019), gives the resulting agency the task of collecting information, and not enough capacity to anticipate and address public health challenges more broadly. More specifically, this means that the resulting capacity is usually insufficient to address a new crisis.

A review of the history of public health crises illustrates the point. The first group of public health crises confronted by the EU included HIV/AIDS, the rising incidence of tuberculosis associated with HIV/AIDs, food-borne infections, and influenza (Steffen 2012). In the late 1990s, an informal advisory group founded the Charter Group and launched the publication of a

pan-European surveillance bulletin. The sudden appearance of food-borne infections drew attention to infectious diseases, though it mostly involved collecting notifiable data according to a common set of indicators. (Elliott *et al.* 2012). Most of what occurred fell under the label of voluntary sharing of public health data and of setting up an early warning system for infectious disease outbreaks with transboundary implications. Mainly, it remained a loose system of different networks and the EU did not view infectious disease outbreaks as a major health threat (Deruelle, 2016). In 1995, the Commission, WHO-Europe, and member states introduced EPIET -- European Program for Intervention Epidemiology Training -- to train a cadre of senior epidemiologists to share common methods and approaches (Liverani & Coker 2012; Reintjes 2008). EPIET Fellows, their supervisors, and colleagues from national training institutes formed a network of epidemiologists who were committed to coordinating the surveillance of communicable diseases in Europe.

By the late 1990s, different networks of experts in epidemiology/infectious diseases operating at the national and international level coalesced to persuade the Commission to fund a pilot platform through which national centers for communicable disease control could connect (Jacobson, 2012). The idea was to establish a European Center for Disease Prevention and Control (ECDC). an independent agency to identify, assess, and communicate current and emerging threats to human health from communicable diseases.

Ultimately, an external crisis convinced the Commission and member states to proceed with the creation of this new agency. The immediate trigger was the SARS (Severe Acute Respiratory Syndrome) outbreak in 2003. Fear of this new corona virus and its high fatality rate gave the final push to sign off on the blue print drafted by the Commissioner of Health to establish ECDC.

Because SARS was likened to the devastating 'Spanish flu' of 1918–1920, the Commission called for a swift decision to establish the ECDC in Stockholm in 2005 (European Union 2004; Greer 2012). In the end, SARS was less contagious and less lethal then anticipated and more or less bypassed Europe. However, Commissioner for Health and Consumer Protection David Byrne, in 2003, stressed how a pandemic in a region with open borders and millions of crossings daily both in and outside the EU, an influenza pandemic could have catastrophic consequences (European Commission, 2003). The European Parliament endorsed the Commission's proposal and the result was the establishment of a fresh agency instead of reinforcing existing scientific networks. For the Commission, the agency would be a solution to the stream of negative news hitting Europe about deadly influenza, anthrax attacks, SARS, and bioterrorism. At the same time, its proposed structure was such that national public health agencies in the member states retained control over the actual response to a pandemic and reflected clearly an institutional compromise (Greer & Löblová 2017). The agency would not engaged in management of risk such as stockpiling vaccines. Such measures remained under the control of the member states (Deruelle & Engeli 2021).

The ECDC was viewed as a major achievement, although its scope and authority were limited from the beginning. Mostly, ECDC engaged in collecting, collating, and analyzing epidemiological data, providing scientific opinion, training and technical assistance, and furnishing risk assessment. It incorporated EPIET (now named ECDC Fellowship Program), and the ECDC also took charge of the peer-reviewed scientific journal *Eurosurveillance bulletin* (https://www.eurosurveillance.org). The ECDC is foremost a center of information gathering and lacks regulatory capacity. It excludes risk communication and management which are delegated to the member states. Its main task is to monitor communicable diseases and assess risks while

disseminating its findings. It relies on outside participants and networks because its staff is small (Rosenkötter, et al. 2013). A quick comparison among the budget and staff sizes of the ECDC as compared to similar agencies in several countries, as indicated in Table 1, illustrate the point.

(TABLE 1 About Here)

In the debate, the new ECDC was likened to the U.S. Center of Disease Control (CDC). While the CDC has legal powers and covers a wide range of public health areas through its bodies such as the National Institute for Occupational Safety and Health or the National Center for Health Statistics, the European Center for Disease Prevention and Control mostly collects and disseminates data on infectious diseases. For this reason, the CDC also has a much larger budget than the ECDC (approximately US$8 billion for 2020, whereas the ECDC operated with a budget of €82 million) and the CDC has a much larger staff (10 796 employees in 2018), versus 271 people employed by the ECDC in that year (European Court of Auditors, 2021). Thus, the origins of the ECDC demonstrate the argument that the ECDC came about in the wake of a crisis and that its capacity was modest and it was given circumscribed responsibilities and insufficient resources to carry out its limited mandate.

In short, the EU expanded its activities in the last 20 years to deal with the next 'big one' though many initiatives were, unfortunately, voluntary, underfunded, and mostly intergovernmental. In retrospect, these initiatives did not build capacity and did not lay the foundation for dealing with an actual pandemic. Two major stumbling blocks stood in the way. Legal basis for EU initiatives is and remains weak. The EU can pursue public health objectives through the integration of the internal market, using Article 114 as the legal basis. It is subordinate to economic integration.

Second, the member states are protective of their authority over public health, including vaccinations, containment, and mitigation of infections. Many member states developed their own infectious disease infrastructure and were hesitant to 'upload' the responsibility of protecting the population against communicable diseases and other health threats to the EU. Together, these explain why the resulting EU administrative structure was unable to meet the original expectations of the advocates of reform. To understand how these EU public health initiatives, resolutions, and programs fared in the post-2005 era, the next section looks at pandemic threats during the functioning of the ECDC.

How the ECDC Handled Early Pandemic Threats

Prior to COVID-19, the world faced several potential pandemic threats and the response of the ECDC consistently fell short due to the limited tools it was given. In 2006, panic roiled the advanced industrialized world with the prospect of avian influenza, which could mutate and become highly transmissible between humans. Anticipating its arrival in the EU, the Commission called for a stockpile of antiviral drugs for use in case a pandemic would erupt. DG Health and Food Safety (DG Sante) made the argument that an anti-viral stockpile would give the EU member states time to organize and mitigate the consequences of the pandemic. However, some member states absolutely opposed the idea of a European stockpile while others felt that the costs of the stockpile should be borne by the EU and not be absorbed by national budgets. Ultimately, the Commission was defeated in the battle to prepare for the next big pandemic by stockpiling antivirals (Elbe, Roemer-Mahler, & Long 2014).

In 2009, another pandemic scare emerged when the H1N1 influenza virus (swine flu) was identified. The Commission launched a concerted effort to organize a stockpile of antiviral medication in order to be prepared when and if the pandemic would spread to the member states. But there was no agreement among the member states how or what to stockpile. The situation became chaotic as some member states, acting alone, hoarded way too much anti-viral medication (Tamiflu) while others were under-supplied and the Commission had no mechanism to solve this dilemma. A better approach would have been to delegate the task of stockpiling anti-viral medication to the Commission but it was prevented from entering into negotiations with pharmaceutical companies which would have pooled power of the member states against pharma (CEC, 2009). Instead, national governments bought their own pharmaceuticals, which were in the end not needed because the 2009 H1N1 pandemic was a non-event (Elbe, Roemer-Mahler, & Long, 2014).

Afterwards, civil society organizations and members of the European Parliament questioned the disproportionate response to a pandemic that ended with a whimper. Investigations seemed to suggest that 'big pharma' hyped up the threat of the H1N1 swine flu and convinced national ministries of health to purchase anti-viral medication. The European Parliament called for more safeguards against 'conflicts of interests' and accused national governments of coddling the pharmaceutical sector. Moreover, though some member states spent millions on wholesale vaccinations, other member states did not embark on a vaccination program. The European Parliament called for more coordination and the Commission stressed that haphazard cooperation between member states and pre-existing purchase agreements contracted by national authorities had contributed to the uneven response to the virus (Taylor, 2011).

In addition, the chaos surrounding the roll-out of the flu vaccine in 2009 triggered calls for greater solidarity among the member states. The Commission raised the possibility of creating a system to jointly procure vaccines during a crisis to plan ahead when to purchase vaccines, how much, and where to roll them out. The Council nixed this proposal and proposed a voluntary system in which national governments would have the right to decide the funding, the number of vaccines, and its distribution. They argued that public health and fighting pandemics was the remit of national governments and was too politically sensitive to be left under the control of the EU (de Ruijter 2019).

The Ebola crisis of 2014 again demonstrated the limited capacity of the ECDC and the EU to become involved in a major pandemic. ECDC tried to coordinate but it ran into a host of difficulties. It monitored the situation and supervised contingency plans yet it was not in a position to organize its own risk management plans (it could perform some risk assessment modeling). It did not have the resources to supervise and coordinate national responses to Ebola and national governments did not rely on the ECDC to assist with the preparation of a possible transboundary crisis. In the absence of an explicit mandate or the resources, it did not receive the prerequisite authority to do anything more beyond monitoring the situation. And without direct engagement in the Ebola crisis, it could not perform its coordination tasks (Jordana & Triviño-Salazar, 2020).

Instead of establishing a joint vaccine procurement program, the EU reinforced its responsibility for certain aspect of public health protection by adding new agencies or

committees to the mix, instead of strengthening the administrative capacity of existing agencies. In 2013, in the aftermath of the swine flu outbreak (The 2009 H1N1 influenza virus), the intergovernmental Health Security Committee (HSC) (Decision 1082/2013/EU) was elevated in order to promote more effective collaboration and the sharing of information to address cross-border threats to health among member states. One new requirement was that public health authorities had to report on their emergency planning and preparation every three years. In this fashion, the ECDC could remain up to date concerning the resources and contingency plans of the member states. Moreover, DG ECHO (European Civil Protection and Humanitarian Aid Operations) set up the Civil Protection Mechanism (CPM), which facilitates cooperation between member states in the event of a disaster (Brooks and Geyer, 2020). In 2019, the EU strengthened RescEU to deal with natural and humanitarian disasters faced by various member states (Greer et.al. 2019). RescEU set up a Civil Protection Pool to collect various assets of each member states which could then be marshalled when a member state requested assistance. All of these programs are part of DG ECHO (Schomaker, Hack & Mandry 2021).

Lack of Preparation for the Next Big One

Not surprisingly, the shortcoming of the ECDC and the EU during previous pandemics became glaring again during the first phase of the COVID pandemic (though the EU failures in this area were hardly unique!). Alongside the U.S. and other advanced industrialized states, the EU did not view the pandemic as a major crisis in the very beginning. As the situation deteriorated, coordination and joint action also faltered because national governments took their own decisions by relying on national experts and drawing their own conclusions on how to deal with

the pandemic, resulting in such measures as closing of borders. Likewise, the intergovernmental Health Security Committee was left out in the cold because meetings were infrequent and poorly attended in the initial weeks of the crisis and many member states had not reported on their preparedness and response plans as required every three years (Beaussier and Cabane, 2020). This situation was not surprising because the HSC was based on a decision that states "member states shall consult each other… with a view of coordinating their efforts…" The HSC does not issue binding provisions and the Decision mostly relies on soft law arrangements, such as the sharing of best practices, guidelines and technical assistance. Other programs that were set up to deal with a big natural or man-made disaster also faltered. The program created by DG ECHO -- the Civil Protection Mechanism -- was supposed to assist during disasters through the Emergency Response Coordinating Center, preparedness training programs and large-scale exercises. In 2019, the CPM was strengthened with the creation of a reserve of additional capacities (RescEU) that notably included medical teams and evacuation capacities. To be sure, the Civil Protection Mechanism (CPM) was not designed with a universal crisis in mind and it could not cope with the same requests for the same resources coming from all member states at the same time (Brooks & Geyer, 2020). None of the previous mechanisms and procedures operated the way they were envisioned because their staff, funding, and operations were too skeletal to be of much support while member states had made no investments in ensuring that these programs and committees would be able to manage the coordination of COVID-19 pandemic. Subsequently, the ECDC, together with the Commission, was sidelined as national authorities did not even bother to share procedures and protocols (Alemanno, 2020; Schomaker, Hack & Mandry 2021).

Eventually, through learning and coordination, mitigation measures began to converge and the initial chaos and 'selfishness' abated (Brooks, de Ruijter, and Greer, 2021; Dimitrakopoulos & Lalis 2021). Nonetheless, during the first three months, member states remained protective of their authority over public health and were unwilling to delegate oversight and competencies to the ECDC (Beaussier and Cabane, 2020). In a critical report published in March 2021, the European Ombudsman attributed the failures of the ECDC mostly due to its lack of resources, staff, and mandates (European Ombudsman, 2021). The report pointed out that it was overly reliant on the goodwill of national authorities and international partners to obtain data. While member states are obliged to provide the ECDC with available scientific and technical data relevant to its mission, during the height of the crisis this obligation was widely ignored. National health authorities performed disease surveillance at the national level but they did not necessarily share this information with the ECDC, which was unable to provide timely and relevant advice to the public health authorities in the member states. Its mission has been limited to surveillance across Europe, training and improving technical quality of epidemiology, diffusing information about disease outbreaks, and helping coordinate responses. Yet coordination, collecting information, and even surveillance failed because it was highly reliant on the resources and support of national epidemiological centers, which possessed their own competencies and were not dependent the reporting and assistance of the ECDC (Greer and Jarman 2021).

The Pandemic Crisis and its Aftermath

Possibly, the EU's legal basis for health already permits considerable action where this is supported by political will, though there is no appetite to introduce formal treaty changes to

expand EU health activities (Clemens and Brand, 2020; Pernhagen, et.al. 2020.). Yet the President of the European Commission, Ursula von der Leyen, urged political leaders to adopt a slew of measures and programs to address the shortcomings revealed during the crisis (European Commission, 2020a). In fall 2020, the Commission presented a finished draft, introducing the European Health Union, while drawing from the lessons learned during the Covid-19 pandemic: better protect the health of citizens; equip the EU and its Member States to prevent and address future pandemics; and improve the resilience of Europe's health systems. To achieve these goals, the Commission laid out a set of steps such as improving the European Medicines Agency (EMA), upgrading the European Center for Disease Prevention and Control (ECDC), creating a regulation that would make ad hoc emergency measures permanent, and formulating an European Pharma Strategy to avoid shortages of critical drug ingredients, medicines and medical devices (European Commission. 2020b).

The pandemic coincided with the preparations of the EU's multiannual (2021-2027) financial framework. The Commission pushed hard so that Health would receive a larger slice of the budget, and the Council and Parliament approved in March 2021, under Regulation (EU) 2021/522, to set aside €5.1b for Health, which is ten times the size of any previous allocation to the health portfolio. Around 12.5 percent of the budget will go towards procurement to supplement national stockpiles of crisis relevant products and another 12.5 percent will go towards supporting global commitments and international health initiatives.

In terms of communicable diseases, the Commission argued for enhancing the powers of the ECDC to issue recommendations on health threats and coordinate with the (intergovernmental)

HSC to manage threats to health. This would be an important expansion of ECDC's jurisdiction because its mandate (Regulation No 851/2004) restricts ECDC to the surveillance of risks to human health from communicable diseases. It specifically excludes risk management (Greer and Mätzke 2012). Treatments such as vaccination and non-pharmaceutical interventions such as quarantines, face masks, or social distancing have remained the prerogative of national authorities. With its 'post-pandemic' proposal, the Commission seeks to exploit the existing legal framework to beef up Europe's public health administrative capacity and policy tools (Deruelle & Engeli 2021).

Under the EU Vaccine Strategy, adopted in June 2020, the Commission negotiates, procures, and distributes vaccines to the member states. It does this by forming a steering committee, which in turn appoints a negotiation team, consisting of Commission officials and representatives of a handful of member states. Its budget is about €2.75b. To make this more permanent, the Commission proposed Health Emergency Preparedness and Response Authority (HERA) in February 2021 to grant the Commission the legal authority to respond to future emergencies. HERA would be tasked with developing a "surge capacity" in production for times when raw materials from outside of Europe might be scarce. It would be based on a public-private partnership to finance vaccines, genomic sequencing, and to design production sites. HERA emulates the US BARDA (Biomedical Advanced Research and Development Authority) which can funnel billions of dollars to the private sector in order to deal with public health emergencies by accelerating the development of the necessary vaccines, drugs, therapies, and diagnostic tools.

Alongside HERA, the Commission also laid out a Pharmaceutical Strategy to address the over reliance on third-country medicine production. Unveiled in fall 2020, it aims for strategic autonomy in the field of drug manufacturing and to avoid protectionist measures imposed by other producers on life-saving drugs. In addition, it seeks new incentives to address unmet medical needs such as rare diseases and pediatric cancer and antimicrobial resistance. EMA plays a critical role as it is supposed to liaise with the drug companies and identify shortages and supply bottlenecks in order to enable action (European Commission, 2020c).

In short, the Commission proposed (and obtained) a larger budget for Health, broader capacity for two agencies (ECDC and EMA), institutionalization of joint vaccine procurement and structured coordination to address shortages of critical drugs and pharma ingredients, and a long term strategy to shore up drug manufacturing in the EU.

Failing forward? Back into Place?

Several decisions have been made that change, at the margin, the EU Health space. At the same time, once the worst phase of the COVID-19 crisis had receded, national governments also retreated from their erstwhile impulse to strengthen the powers of the EU to intervene during a global health crisis.

HERA, which was supposed to mirror the U.S. BARDA, is in fact an administrative unit in the Commission itself. Its board will represent the member states and it will remain intergovernmental because it specifically excludes representatives of the European Parliament (Peseckyte 2021). With a budget of €1.3 billion for 2022, the new authority will steer coordination of national strategies and it will be performing the same functions Commission officials fulfilled during the pandemic. It will be tasked with "the development, manufacturing, procurement, and equitable

distribution of key medical countermeasures." It promises to consult with the ECDC, and EMA and other stakeholders. But its actual operations will be exempted from scrutiny since it is embedded in the Commission and its budget is rather modest (Holmgaard Mersh, 2022).

The second step that has been taken is to broaden the powers of EMA. The provisional agreement, struck in January 2022, will lead to a European Shortage Monitoring Platform to collect information on shortage of medicine and medical devices and post this information on a website. To do so, the EMA will create two "shortage steering groups" one for medicines and one for medical devices and work closely with the drug companies, representatives of patients and wholesale distributors (European Parliament, 2022).

One potential drawback is the EMA's dependence on the drug companies which are supposed to share information voluntary and are supposed to inform EMA about potential shortages of ingredients, development of drugs for orphan diseases, the number of patents and their expiration date, and their marketing objectives and other R&D steps. In short, big pharma will not be obliged to notify the EMA of any changes in its supply line, research objectives, and sources of its pharmaceutical ingredients, the number of patents they have and when they expire, and if they want to market their products in the EU. Not surprisingly, industry objected to sharing 'proprietary' information, fearful of compromising its competitiveness, marketing strategies, and research developments (Collis, 2022). The Council agreed with this assessment and diluted the original proposal.

Thirdly, negotiations have resulted in an agreement to reform the ECDC though the reforms are fairly small and will most likely not alter its competencies and its relationship with its

counterpart in the member states. The Commission set forth a proposal so that the ECDC could engage in epidemiological surveillance in real-time; take on response planning, reporting and auditing; issue non-binding recommendations and options for risk management; build up capacity to mobilize an EU Health Task Force to assist member state responses, and build a network of EU reference laboratories. The EP Committee for Environment, Health, and Food (ENVI) introduced many amendments to the Commission proposal in September 2021, including mandatory guidance for member states, direct assistance for member states to improve their health systems capacities by introducing common indicators and definition to ensure comparability, and add surveillance and information gathering of the incidence of non-communicable diseases (cardiovascular and cancer) in the EU (Kopcińska 2021). Moreover, the ENVI report proposed that the ECDC should have a right to organize regular visits to the Member States to assess health systems' capacity to manage health crises and to organize ad hoc inspections to the member states to verify preparedness and response plans! (Scholz, 2020; European Parliament, 2021).

However, the Council expressed reservations concerning a dramatic extension of ECDC's mandate and three inter-institutional trilogue negotiations yielded a compromise that stripped the ECDC of its "a more supervisory and prescriptive role", and that reinforced its supportive or complementary mission. The Council also vetoed the suggestion that the ECDC (like the U.S. CDC) covers non-communicable diseases. Instead, the compromise extends the mandate of the ECDC to improve coordination by harmonizing data collection and modelling. It will also develop risk assessment and maintain databases for epidemiological surveillance, and the ECDC is encouraged to cooperate with EU bodies and national and international counterparts closely. It

will supervise the EU Health Task Force of experts to assist with preparedness and response planning, monitor the capacity of national health systems to detect, prevent, respond to and recover from communicable disease outbreaks (Popp, 2021)

In early 2022, the EP had to accept major concessions, with the result that the 'new' ECDC still plays a 'supportive' role in assisting public health authorities in the member states. It specifically proscribed imposing harmonized standards for data collection (Nielson, 2021). While the ECDC received broader mandate to collect and analyze more data and information, national health authorities must supply that information, something that they failed to do in previous years. As a Danish Health Minister Magnus Heunicke noted: "The future framework must fully respect national competence and the responsibility of member states" (Deutsch, 2021).

Conclusions

The European health union, among other things, is aimed at addressing serious cross-border threats to health by strengthening existing EU agencies, data sharing between Member States and give the EU the power to declare emergencies. Some of that will happen, but the EU Health landscape has not dramatically changed.

When viewing the economic-financial steps taking during the pandemic, it could plausibly be argued that the EU is failing forward. But we look at the likelihood of strengthening and deepening European Health Union in response to the COVID-19 epidemic. Applying the "failing forward" argument to the case of a major public health crisis, we noted that the EU's administrative capacity to act in this area is weaker than in policy areas related to the EMU. We also pointed out that previous crises (influenza scares) did not substantially reinforce EU remit

and mandate to protect EU citizens from infectious diseases. Although EU health has gained in visibility and is better funded than any other time in Europe's history, institutional and capacity building in this area resembles a pattern of vigorous activity and bold proposals in the heat of a crisis, but a failure to complete the plans once the crisis had just about abated. The more powerful capacity continues to reside within the member states, limiting the power of such agencies as ECDC and HERA to little more than soft law instruments of coordination.

We found that EU health agencies were not afforded the administrative capacity that would allow them to quietly build a stronger European profile after the immediate crisis had passed. Low capacity agencies proved weaker in handling future crises when they erupted. For example, the European Center for Disease Prevention and Control (ECDC) failed at the onset of the pandemic, mostly because the agency was hampered from the beginning in coordinating a European response. Since its inception in 2005, member states have been protective of their jurisdiction over public health and have blocked agreement to create emergency structures which were not seen as a public good (Jordana and Triviño-Salazar 2020).

Weak administrative capacity proved significant for the case of the EU and allowed us to identify another pattern which we describe as "failing to complete." This pattern is characterized by an issue gaining great attention during a crisis, but then falling back out of attention once the crisis is past.

Table 1: Selective Infectious Disease Agencies, EU and U.S.*

AGENCY	STAFF	BUDGET
European Center for Disease Control and Prevention (ECDC)	271 (2020)	€82m (2020)
German Robert Koch Institute (RKI)	1300 (2016)	€80m (2016)
France Santé Publique	1024 (2019)	€195.5m (2019)
Dutch Rijksinstituut voor Volksgezondheid en Milieu (RIVM)	1800	€345m (2019)
Swedish Folkhälsomyndigheten (Public Health Agency of Sweden - PHAS)	450 (2014) & 600 (2020)	SEK 345m (= €38m in 2014)
U.S. CDC	15,000 (2021)	$11.9b (2018)

*These agencies are not fully comparable because they are charged with different missions/functions. For example, the Dutch RIVM also manages emergency response services and local public health clinics (GGD).

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