EU Recovery Plan and National Health Systems

A comparative overview of France, Germany and United Kingdom*

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SUMMARY: Some introductory remarks. – 1. France: confirmation of a broad interpretation of the *droit à la santé*. – 2. RFT: the Germans are suffering too … – 3. UK: Man shall not live by Brexit alone … – Some conclusions.

Some introductory remarks

The worldwide upheaval brought by the Covid-19 pandemic was clearly assumed to affect also, and in some respects above all, health systems and, more generally, the relationship between health protection and the organisation of health services. If, during the first waves of the emergency, attention was mostly focused on how the various systems would have withstood the impact of a phenomenon for which there was a generalised

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unpreparedness,[1] there subsequently prevailed, on the one hand, an interest in investigating the organisational solutions that would best enable us to combat similar phenomena in the future and, on the other, to 'take advantage' of the hard lessons learned while providing for an in depth reorganisation of the entire supply chain of health-related services.[2] Here, I would particularly like to address the issue concerning the continuities and discontinuities that are affecting the approach of some European legal systems by referring to the relationship between the right to health and the organisation of health services. Thus, the examination of the characteristics and effects of the health emergency, as it appeared in comparative law, remain outside the perspective investigated here.[3] I would also like to specify that, on the basis of the general topic of the seminar, in order to identify the essential features of the theme, I will be using some National Recovery and Resilience Plans (or equivalent designations) as basic documents, taking into consideration in particular those jurisdictions for which, by virtue of the consonance of approach to the right to health, the comparison would be most fruitful. Therefore, not all the legal systems will be examined in our seminar, but only some of them.

The backdrop to my reflections is naturally the Italian experience of the National Health Service, whose distinctive features in the European panorama and whose responses to the pandemic stress-test[4] are presumed to be sufficiently well known: the so-called Italian "*Costituzione sanitaria*" and the following ordinary regulations, which I will refer to when necessary, have been described several times in recent years, even by me. At the outset, however, I would like to emphasise that the basic features of our healthcare system have remained unchanged even during a difficult two-year period, 2011-2013,[5] in which Article 1 of Decree-Law No.158/2012, dedicated to the reorganisation of territorial healthcare, was

[1] R. Balduzzi, *La questione sanitaria e i conflitti di competenza nell'emergenza pandemica*, in N. Antonetti, A. Pajno (a cura di), *Stato e sistema delle autonomie dopo la pandemia*, Bologna, il Mulino, 2022, 29.

[2] R. Balduzzi, *Cinque cose da fare (e da non fare) in sanità nella (lunga e faticosa) transizione verso il post-pandemia*, in *Corti Supreme e Salute*, 2/2020, 339 ff.

[3] On this point, interesting methodological considerations in F. Balaguer Callejón, *Diritto dell'emergenza e pluralismo territoriale nel contesto europeo*, in G. D'Ignazio, A.M. Russo (a cura di), *I* Federalizing Process *europei nella democrazia d'emergenza. Riflessioni comparate a partire dai 'primi' 20 anni della riforma del Titolo V della Costituzione italiana*, *DPCE online*, vol. 54, no. spec., November 2022, 27 ff. The importance of circumscribing the field of comparison on the forms and ways in which the Covid-19 pandemic was contended with in different jurisdictions, and the need to consider «*la contingence, sur laquelle aucune gouvernance ne peut avoir de prise*», see P. Sadran, *Comment évaluer la qualité de la gouvernance face à la crise sanitaire de la Covid-19?*, in *Revue génerale de droit médical*, 2021, 227 ff.

[4] On the pandemic as a *stress test*, see R. Balduzzi, *Cinque cose da fare (e da non fare) in sanità*, cit., 339, and A. Vedaschi, *Il Covid-19, l'ultimo* stress test *per gli ordinamenti democratici: uno sguardo comparato*, in *DPCE online*, 2/2020, 1456.

[5] In the course of which, in the face of a dramatic economic-financial situation of the entire country, the health sector nevertheless managed to express capacity for self-assessment and a willingness to redeem itself: consider, in particular, the part dedicated to health care of the so-called spending review (Article 15 Law Decree No. 95/2012, which, among other things, gave rise to the hospital standards provided for in Ministerial Decree No. 70 of April 2, 2015, and considered specifications of the essential levels of care) and to Decree Law No. 158/2012, significantly entitled *Disposizioni urgenti per promuovere lo sviluppo del Paese mediante un più alto livello di tutela della salute*.

the *pendant* of the coeval hospital reform, confirming the unity of the network of social and healthcare services, divided into a hospital sub-network and a territorial sub-network.[6] The Italian health system is therefore one that, over time, has been able to perform with limited resources,[7] and yet today, after three years of pandemic, it is going through profound difficulties and anxieties that concern, at the same time, its sustainability and the permanence of its strong core of the principles of universality, globality, fair accessibility and financing through general taxation that have characterised the system since the law establishing the National Health Service (*Sistema Sanitario Nazionale – SSN*).
Despite the articulation of the various scientific positions, there is substantial consensus in the specialised doctrine on the following assumption: the pandemic certainly saw (also) the Italian healthcare system[8] unprepared. Its limitations, however, were attributable not so much to the features and to the architecture of the *SSN*, but rather to their inexistent or insufficient implementation. Once we clear the field of the inaccurate representation of a shortage of intensive care units resulting from the alleged 'cuts' of past decades,[9] we realise that the main weaknesses were concentrated in two areas a) in the area of territorial assistance, including socio-healthcare integration, *i.e.*, precisely in the area where the reform effort had been strongest, both in 1999,[10] with regard to socio-healthcare integration, and in 2012, with regard to general practitioners; b) in the problematic connection between the various levels of government, in particular between the State and Regional levels.
The Recovery Fund and the Next Generation EU programme constituted a clear change of scenery and the resulting *Piano Nazionale di Ripresa e di Resilienza* (PNRR) benefited

[6] In a similar sense, see I. Ciolli, *La salute come diritto in movimento, Eguaglianza, universalismo ed equità nel sistema sanitario, oggi*, in *Bio-Law Journal, Rivista di BioDiritto*, 2/2019, 13-33.

[7] See the data recently revealed and commented on CREA, *XVIII Rapporto Sanità – Senza riforme e crescita, SSN sull'orlo della crisi*, a cura di F. Spandonaro, D. D'Angela, B. Polistena, Roma, 2022.

[8] The pandemic has revealed, in our as in other countries (see the writings collected in *DPCE on line*, 2/2020, edited by A. Vedaschi and L. Cuocolo), a generalized unpreparedness (of science, politics, administration, individuals). The affair of the plane with a cargo of 18 tons of masks leaving Brindisi for China in mid-February (see, on this point, P. Perulli, *Nel 2050. Passaggio al nuovo mondo*, Bologna, 2021, 152) is both a sign of solidarity and a symptom of lack of awareness. The reasons for that unpreparedness go beyond health policy choices, and pertain to cultural profiles whose examination is beyond the scope of this paper ("presentism", the habit of living in "real time").

[9] I echo what was pointed out, in the first months after the pandemic outbreak, in Five things to do (and not to do) in health care, cit, 342 (note 14): with regard to the number of intensive care beds (in public and accredited facilities), it is sufficient to consult the statistical yearbooks of the NHS to note that, between 1997 and 2017, it increased overall, according to a trend that did not change sign following the application of Ministerial Decree No. 70/2015 and that was confirmed (with about 5100 places) when, in the first days of March 2020, the expansion plan was launched that would lead to almost doubling them within a few weeks (there were 4996 in 2017, the reference year of the last available yearbook, published in 2019). See, now, the data and commentary contained in the Report to Parliament on the Financial Management of Regional Health Services. Fiscal Years 2020-2021, deliberated by the Court of Auditors, Section of Autonomies, on December 19, 2022 (of No. 19/SEZAUT/2022FRG).

[10] On the subject of social and health integration, see the collected writings in *Corti Supreme e Salute*, 2/2018, 245-376, introduced by my *La persona in tutte le politiche (sociali): una "scommessa" quasi compiuta. Presentazione di un Convegno sul socio-sanitario e della correlata ricerca*, 245-248.

from it.[11] In the perspective of effective socio-healthcare integration, I have already tried to identify some corrective measures to be taken with the PNRR itself and some suggestions for its interpretation and implementation,[12] some of which were adopted by Ministerial Decree No. 77 of 2022: firstly, the provision of the compulsory presence, within the Community Home (*Casa della comunità*), of social workers, who must be integrated into the multidisciplinary team together with general practitioners and paediatricians, specialist doctors, community nurses and other health professionals, so as to ensure that a single access point (*punto unico di accesso*) can assess and take charge of the necessities upstream and downstream. Second, the advisability of linking the experimentation referred to in Article 1, paragraph 4-*bis* of Law Decree No. 34/2020 with the investments concerning the Community Homes,[13] so as to allow the development, during the experimental phase,[14] of an organisational model consistent with the territory of reference and with the indications of the PNRR (though this indication was not particularly developed in Ministerial Decree no. 77, it goes without saying that, also in consideration of the - at least apparent - coldness that the current executive seems to have towards a strong model of Community Homes,[15] focusing on the good practices already implemented on an experimental basis seems to be quite wise). At least on paper, then, Ministerial Decree no. 77 assigned an important role to the coordination tasks of the Ministry of Health, going beyond the hesitancy with which the abovementioned paragraph 4-*bis* was implemented (and thus interpreting those powers in a reductive sense, as a mere prediction of the general characteristics of the proximity structures and a guarantee of the proper allocation of resources), and emphasising its

[11] Regulation (EU) 2021/241 of the European Parliament and of the Council of Feb. 12, 2021, establishing the Recovery and Resilience Facility (RRF Regulation) with the specific objective of providing Member States with financial support in order to achieve the interim milestones and targets for reforms and investments set out in their recovery and resilience plans; for all see M. Clarich, *Il piano nazionale di ripresa e resilienza tra diritto europeo e diritto nazionale*, cit.

[12] See R. Balduzzi, *Il diritto alla salute durante e dopo la pandemia*, cit., 52-54.

[13] The Plan calls for the activation of 1350 Community Homes by mid-2026, with the possibility of using both existing and new facilities, at an estimated total cost of 2 billion: by far, therefore, the largest investment in the health sector ever planned, which reinforces the need for the health, social and socio-health profiles to be integrated to prevent the outcome of the investment itself from being reductively confined to health housing alone, but, indeed, allow for the creation of facilities that make it possible to counteract situations of vulnerability through pathways of continuity of care and co-responsibility of the recipients of care and the community contexts of reference, so that the most fragile people are put in a position to cope with both ordinary situations of distress and illness, as well as emergency situations. It goes without saying, then, that health care building interventions cannot fail to be thought of in close coherence with the other directions of the Plan, particularly those of environmental sustainability.

[14] On the importance of overthrowing the top-down model and thus on the essential role of experiments at the territorial level, aimed precisely at favouring a model based "on the circularity of decision-making processes, no longer top-down in the specification of action, of ways of acting, but capable of expressing actions that are the result of co-decision-making that builds programming and programs from the bottom up (the reverse of the classical model of the 1970s)," I am pleased to recall the pages of P. Carrozza, *La «Società della Salute». Il modello toscano di gestione integrata dell'assistenza sociale e della sanità territoriale alla luce dei princìpi sanciti dagli artt. 5, 32 e 118 Cost*, in *Il rispetto delle regole. Scritti degli allievi in onore di Alessandro Pizzorusso*, Torino, 2005, 143.

[15] *E.g.*, see the speech by Undersecretary for Health Marcello Gemmato, reported by www.saluteinternazionale.info of the 5 December 2022.

role as a committed and active playmaker, also by stimulating the preparation of the basic tools to be able to correctly read the needs of a territory and adapt the requirements of the facilities deputed to meeting them.

This last premise concerns the theme of continuity/discontinuity between the structural changes induced by the pandemic experience (and included in the choices contained within the various national recovery and resilience plans) and the reforms initiated or announced, within the individual systems, in the health sector prior to the outbreak of the pandemic. Since the answer to this question will be set out on the basis of documents with strong discursive and political-cultural characterisations such as the abovementioned Recovery and Resilience Plans,[16] it will be my concern to exercise the utmost care in my diachronic analysis, in order to avoid or mitigate a possible trick with mirrors linked to the eventual different composition of the political majority that formed and negotiated the plan compared to the one in power prior to spring 2020, also taking into account that the public-comparative scholarship tends to not focus extensively on such political-governmental dynamics.[17] Therefore, I will deal with the French and German situations, with a few references to the British experience, aimed at verifying similarities and differences in a system that by definition is foreign to the dynamics triggered by the Next Generation EU.

A first distinction should be made between systems that took the opportunity of the pandemic to review, in whole or in part, the structure of their healthcare service and systems that preferred to insist on projects capable of strengthening it, without however touching its fundamental profiles. The Italian choice went in the first direction (even though the determination to pursue the reform objectives set out in the PNRR seems to have waned with the new Legislature and the new Executive)[18] and that, without neglecting the profile of investments related to telemedicine and, more generally, to digital healthcare, the focus of the Italian response to the shortcomings highlighted by the pandemic was to reorganise territorial healthcare.

[16] In Italian doctrine, on the legal nature and technical-formal characteristics of NRRP, see especially M. Clarich, *Il PNRR tra diritto europeo e nazionale: un tentativo di inquadramento giuridico*, in *Astrid Rassegna*, 2021, and N. Lupo, *Il Piano Nazionale di Ripresa e Resilienza (PNRR) e alcune prospettive di ricerca per i costituzionalisti*, in *Federalismi*, 1/2022. Lastly, F. Polacchini, *I riflessi del Pnrr sulla forma di governo e sui processi di indirizzo politico*, in *Forum di Quaderni Costituzionali*, 4/2022.

[17] With a few commendable exceptions, such a., J. Woelk, *I sistemi federali di Germania e Austria alla prova dell'emergenza pandemica*, in *I* Federalizing Process *europei*, cit., 329 ff. Sometimes the relationship between pre- and post-pandemic decisions is even more articulated, as the national system may tend to emphasize a kind of primogeniture with respect to certain structural reforms, as is the case for France with Compound 2 of the Plan, on ecological transition and circular economy.

[18] Back, text and note 43; see also the statements of the Minister of Health *pro tempore*, made at a hearing before the competent parliamentary commissions on 6 December 2022.

1. France: confirmation of a broad interpretation of the *droit à la santé*

The French experience went in a direction that is both similar and different to what happened in Italy. The underlying concern was quite similar to the Italian: without structural interventions that implement a healthcare network capable of integrating hospital and territorial healthcare (*soins hospitaliers* e *soins de ville*, to which a third category was added, that of the établissement médico-social*),*[19] where the long-term resilience of the healthcare system could not be ensured, and this because of the high degree of separation between the hospital and the territorial sub-network.

It should be noted that, differently from the Italian analyses, which emphasised extensive situations of lack of efficacy and effectiveness of the territorial sub-network, the element most invoked in the French context (see *composante* no. 9) was that of the increase in costs that this separation entailed and the consequent loss of efficiency. This different analysis led to a different reform strategy, focused on the one hand, on the modernisation of hospitals, Établissements socio-médicaux (residential and semi-residential facilities for the elderly, disabled or otherwise disadvantaged, ESSMS) and Établissements hébergeant des personnes âgées dépendantes (EHPAD),[20] and, on the other hand, on the growth of digitalisation in order to avoid or reduce the separation between the two sub-networks.

From these initial remarks, one might get the impression that the French legal system had set up a strategy aimed not so much at integrating hospital and territory, but at accelerating the structural modernisation of healthcare facilities and their technological efficiency, also in relation to the strengthening of digital health. A closer examination, however, allows us to read this choice as being absolutely consistent with the recalled underlying concern of strengthening the link between *ville*, hôpital and *médico-social*, and this on the strength of a multiplicity of reasons.

First, because the funds for the structural modernisation of buildings destined to strengthen health services were divided into two categories, one relating to *courants* investments and the other to *structurants*[21] investments, and for access to the latter it was indispensable, among other things, that the project be able to demonstrate the aptitude to improve care pathways and the *ville-hôpital* link, as well as to reduce territorial imbalances. Second, because France did not get a break, but rather a common treatment for hospitals, clinics, *ESSMS* and *EHPAD* (and we find eloquent confirmation of this in the circumstance that the public database of health and social facilities, the *Fichier national des établissements*

[19] We could, with some approximation, liken this category to Italian assisted living residences.

[20] On these two categories of établissements, see A. Laude, B. Mathieu, D. Tabuteau, *Droit de la santé*, 2.a ed., Paris, 2009, 244 ff.; more recently, A. Morelle, D. Tabuteau, *La santé publique*, Paris, 2021, 56 ff.

[21] See especially the *composante* 9, no. 5.

sanitaires et sociaux, has included in a single archive, for quite some time, what in Italy we have always called health, socio-sanitary and socio-assistance facilities),[22] according to what both Article L1411-1 of the *Code de la santé publique*, which considers them as unitary subjects of the health policies and integrates *soins*, *prévention* e *compensation du handicap et de la perte d'autonomie* in the care pathways. Then there was Article L61138 et ff. of the same *Code*, introduced by Law No. 2009-879 of 21 July 2009 (on the *réforme de l'hôpital et relative aux patients, à la santé et aux territoires*), which brought all of these subjects under the planning and governance competences of the regional health agencies.[23] These also included the annual social security financing laws which jointly implemented both categories, from the point of view of financing the related expenditure and from that of prevention.[24]

The third reason could be found in the fact that this structural modernisation was exemplified precisely by emphasising the link between *ville*, *hôpital* and *médico-social*, as well as the development of large outpatient facilities *ouvertes sur la ville*. The real estate investment aid programme in the *médico-social sector*, aimed in particular at transforming EHPADs into *véritables centres d'expertise du grand âge* was in the same vein. Finally, with regard to digital health (on this point, both the indications of the EU Commission and the 'internal' evaluations of the French health administration agreed on the need for France to catch up with what had proved to be an historical delay);[25] the approach was to use it, in particular with regard to telemedicine, as a privileged linking tool to ensure what in Italy we call hospital-territory continuity (*continuità ospedale-territorio*).[26]

Systematically, it can be observed that the French post-pandemic approach, at least as it can be reconstructed by the *composante* No. 9 of the Plan, offered confirmation about the extensive interpretation that legislation and implementing regulations had progressively given to the notion of *droit à la santé*, going far beyond health benefits in the strict sense,

[22] Generally known as *répertoire FINESS*.

[23] Whose role with regard to health services is growing, and is little known outside France, due to the cliché that sees the French system as the prototype of the centralized State.

[24] See the *loi de financement de la sécurité sociale pour 2023* (l. n° 2022-1616 of 23 December 2022), on which see *Cons. const.*, dec. n° 2022-845 DC of 20 December 2022. Pursuant to Art. L.O. 111-3-4 of the social security code, this law «*détermine, pour l'année à venir, de manière sincère, les conditions générales de l'*équilibre financier de la sécurité sociale, compte tenu notamment des conditions économiques générales et de leur évolution prévisible». The reference to the necessary "sincerity" of such a law recalls, as for the Italian system, the call for "accompanying legislative initiatives affecting the provision of social benefits of primary rank with an appropriate financial investigation" (Const. Court, decision no. 169 of 2017).

[25] See, in particular, what is reported in the *composante* n° 9.5 of the French plan, about the delay «*dans la modernisation, l'interopérabilité, la réversibilité, la convergence et la sécurité des systèmes d'information en santé*».

[26] See the important No. 10 of Annex 1 to Ministerial Decree No. 70/2015, titled "*Continuità ospedale-territorio*" (Hospital-territory continuity), which already clearly enunciated the choices later merged in the NRRP and in the Ministerial Decree No. 77/2022.

and which French doctrine has long correctly framed.[27] It should also be noted that France has had for some time, especially since the 2019 crisis (characterized by the affair of the so-called *gilets jaunes*), forms of periodic consultation-concertation of stakeholders and, in some cases, of the generality of citizens, on major decisions in the healthcare field and that these have also been referred to in the post-pandemic era. In this sense, the French Plan connected with the experience called *Ségur de la santé*:[28] a semi-permanent round table for health policies, so named after the Parisian avenue where the *Ministère de la santé* is based.[29] This outline of the French experience would be of some interest for the Italian context, where there has been a multiplication of the voices that were denouncing a creeping transformation of the National Health Service, without a national participatory debate having been opened,[30] and where public decision makers and stakeholder organizations, professional and productive, seem to have preferred bilateral agreements.

2. RFT: the Germans are suffering too ...

Compared to the French situation (and, in some respects, the Italian situation as well), the German situation has been characterized by a different reading of the impact of the pandemic. The German Recovery and Resilience Plan (*Deutscher Aufbau- und Resilienzplan*, *DARP*) moved from the premise that, on the one hand, timely lockdown decisions, made in agreement with the *Länder*, and, on the other hand, the operation of territorial tracking and alerting services, as well as the safety net for businesses and employees and self-

[27] See, on this point, for all, A. Laude, B. Mathieu, D. Tabuteau, *Droit de la santé*, 2nd ed., Paris, 2009, 244 ff.; more recently, A. Morelle, D. Tabuteau, *La santé publique*, cit., pp. 2 ff., 297 ff. Then there are open issues and problems that the resources of the NRPs may allow to be addressed, although not directly dependent on the pandemic, but which it has especially highlighted. Consider, for example, occupational safety, with regard to which the Plan devotes special attention, especially to the issue of prevention (*composante* n° 8); For similar attention shown, in our country, see Article 20 of Law Decree No. 36/2022 (*Ulteriori misure urgenti per l'attuazione del Piano nazionale di ripresa e resilienza (PNRR)*), converted into Law no. 79/2022.

[28] In general, for critical considerations of the so-called *grand débat national*, see M. Fleury, *Le grand débat national ou l'illusion du débat*, in F. Politi (a cura di), *Democrazia deliberativa e rappresentanza politica. L'esperienza francese del* débat public *ed il dibattito sulla democrazia in Europa*, Torino, 2021, 69 ff. On *Ségur de la santé*, in particular, see the notations of A. Grimaldi, *Manifeste pour la santé 2022. 20 ans d'*égarements: il est temps de changer, Paris, 2021, 57 ff.

[29] In Italy, something similar are the "States General" (experimented with at various institutional levels, but so far never covering health care), or National Conferences, some examples of which have also occurred in the health care field (recall the 1999 National Conference on Health Care, or, for particular sectors, the 1999, 2012 and 2017 Government Conferences on Asbestos).

[30] See, most recently, R. Bindi, N. Dirindin, *La sanità svenduta in nome del mercato*, in *La Stampa*, 13 January 2023; C.M. Maffei, *La narrazione del "troppo privato" come causa principale dei mali del Ssn rischia di essere fuorviante*, in *Quotidiano Sanità*, 3 February 2023.

employed workers, would have made it possible to provide a rapid and effective response to the health and social threat.[31]
From this premise followed the focus of *DARP*'s attention, in addition to the ecological transition and *Dekarbonisierung* (on a par with all National Recovery and Resilience Plans), on the digitization of the economy and infrastructure, and the resources allocated to strengthening a *pandemie-resilienten* health system, which also went in this direction: these were resources that were significant percentages of the total resources allocated to the different components of *DARP*,[32] but that focused on investments to develop emergency response capacity (especially by promoting accelerated vaccine research and development) and aimed at creating a digital infrastructure, with particular reference to the hospital network.
As much as *DARP* insisted on emphasizing among the objectives of the various measures that of strengthening the resilience of the health care system in general, including through the use of eHealth (as also explicitly requested of Germany by the EU Commission),[33] the focus was primarily, except for what had already been mentioned on the subject of vaccines, on this last aside: the aim of the measure was to "create an interoperable digital infrastructure to network health facilities and other actors in the public health service", where the overriding need was to prevent the boundaries of the *Länder* and the autonomy of the various health institutions (in particular, health insurance funds) from being viewed as obstacles to the accomplished digitization.
This is confirmed by the very component 5.1 of the *DARP*, in the part devoted to the hospitals of the future (*Zukunftprogramm Krankenhäuser*): beyond the very broad wording, the related measures essentially refer to increasing the level of digitization in all hospitals, such as the technical-informatics adaptation of emergency rooms from the point of view of improved accessibility.[34] However, though much emphasis is given in the document to the circumstance that «*eine nachaltige Verstärkung des ŐGD alse eine unverzichtbare Säule des Gesundheitswesens dringend geboten ist*» (in the sense of the urgency to strengthen the public health service as an indispensable pillar of the health care system), the un-

[31] See the first part of *DARP*, *Allgemeine Ziele und Kohärenz des Plans* (where not otherwise stated, translations from German documents are my responsibility).

[32] 16.3%, which is, next to the measure concerning online access to public administrations, the single measure with the highest funding of the entire *DARP*.

[33] *DARP*, general part, no. 2.

[34] The *DARP* states that "The challenge of the Hospitals of the Future Program is to promote a large number of needed investments in hospitals in a short period of time (...). In particular, the digitization of hospitals, which is in need of modernization in many places, must be extended to all, as should cross-coverage between different health sectors. In this context, it is important to put in place a transparent and easily manageable financing system, so that hospitals can benefit quickly and in as many places as possible from financing opportunities, but also that measures are implemented in a targeted and coordinated manner. In addition, teaching hospitals should be eligible for funding (...) The states are responsible for deciding which projects to apply for funding (...). Consulting services and the costs of necessary personnel measures directly related to the projects, including personnel training costs incurred in implementing the funding projects, may also be funded".

equivocal choice made by *DARP* goes in the direction that such sustainable strengthening of the public health service should clearly prioritize the digital infrastructure. Even the "Pact for the Public Health Service" (*Pakt für den Őffentlichen Gesundheitsdienst*) shared between the *Bund* and the *Länder*, although it refers verbatim to all functions of the Public Health Service and to all administrative levels, has at its heart the implementation of already existing tools (this is the case with the Electronic Reporting and Information System for Infection Protection, *Deutsche Elektronische Melde- und Informationssystem für den Infektionssschutz-DEMIS*, created at the *Robert Koch-Institut*, provided for in §14 of the *Infektionsschutzgesetz* and refined in the wake of the pandemic, including through a closer linkage with the pre-existing *Surveillance, Outbreak Response Management and Analysis System* (*SORMAS*), a private nonprofit foundation)[35] and in the shared definition between the federal and sub-federal levels of minimum standards (*Mindeststandards)*[36] that would ensure comprehensive communication and interoperability. Funding from the federal side was matched by a commitment from the states to comply with these shared minimum standards[37], and the federal level equipped itself with a system of indicators[38] to measure the degree of progress of digitization at the level of the individual health facility, to whose ranking the amount of funding granted was correlated.[39] It is to be noted that the *DARP* emphasized that this was not a centralized system (the federal structure of the FRG would not allow this, and moreover, disagreements between and among the *Bund* and the

[35] On this point, see, for information on the current status of the linkage, G. Göpel, *Wie geht es mit SORMAS ab 2023 weiter?*, in *Tagesspiegel background*, 2 December 2022, which highlights the variety of solutions at the level of *Länder*); with regard to DEMIS, it should be noted that *Bund* e *Länder* agreed in 2021 to make it available to all health authorities at federal level and to *Land*. It should be noted that, already in the first months after the outbreak of the pandemic, the federal government had granted the *Länder*, according to Article 104b, § 1, *Grundgesetz*, targeted funding for the digitisation of health offices, based on the *Zweites Gesetz zum Schutz der Bevölkerung bei einer epidemischen Lage von nationalen Tragweite* of 19 May 2020 (the law has been since adapted several times to the changes that occurred during the pandemic: the most recent is the law of 22 April 2021, *Viertes Gesetz*).

[36] Minimum standards integrated into the funding contract and to be developed, and constantly evaluated, within the framework of a research project, whose underlying criteria are those of the *Reifegradmodell* (on which see *infra*, note 81).

[37] If anything, the question pertains to whether the sharing and compliance of minimum standards with them is sufficient to ensure full interoperability (see the paper by Göpel cited in note 78).

[38] The *DARP* and its subsequent update refer to this system as the 'maturity model' (*Reifegradmodell*), developed with the involvement of the *Bundesamt für Sicherheit in der Informationstechnik-BSI* and hinged on eight macro-indicators (digitisation strategy; number of employees; digitisation of processes; IT provision; IT security; citizen-centricity; software sharing; interoperability). It should be noted that this 'maturity model' was, after the approval of the DARP, supplemented on the basis of a comparison between the *Bund* and the *Länder* (G. Göpel, Wie geht, cit.) and that the gradualness in achieving the digitisation targets also involved – component 5.1.9. – the municipalities and cities, given their importance as owners of health facilities (in this respect, the observation of R. Scarciglia, *La ripartizione delle funzioni amministrative negli Stati composti dell'Europa. Il ruolo delle Città nei modelli di sviluppo post-pandemia*, in *I* Federalizing Process *europei*, cit., 163, according to which the *DARP* paid no special attention to cities except for investments in housing stock to combat housing shortages and improve energy efficiency).

[39] For details, see *Tagesspiegel background*, 14 february 2023.

Länder and between the latter, especially at the beginning of the pandemic, were acute),[40] in that the decentralized approach of digitization grants made it possible to "create regionally targeted solutions with regional providers, without having to give up interoperable information flows" (*um auf regionaler Basis passgenaue Lösungen mit regionalen Anbietern zu etablieren ohne auf interoparable Informationsflüsse verzichten zu müssen*).[41]
Subsequent to the approval of the *DARP* and following the entry into office of a new federal executive (November 2021, so-called *Ampelkoalition*, or "semaphore government"), a more general hospital reform was promoted, including changes to funding rules, reclassification of *Krankenhäuser*, restructuring of the emergency system, and a more pronounced focus on outpatient medicine and *Medizinisch-Pflegerischen Versorgungszentren* (facilities quite similar to the Italian *Case della salute*). As of today (March 2023), though the fate of the German hospital reform is uncertain, mainly due to the resistance of some *Länder*, in particular Bavaria, it is nevertheless interesting to note that the underlying reason for this situation has always been essentially financial, namely the need, on the part of the *Länder*, to mitigate deficits, which are growing and are no longer sustainable, by rebalancing the bed occupancy rate, which as a result of the pandemic and the greater propensity towards outpatient care, is on average unable to exceed seventy percent.[42]
It is precisely this last point that makes it possible to carry out some reflections, precisely moving from the examination of the German-federal system, with regard to how the different national systems countered the pandemic and the responses they are giving with regard to the strengthening of health protection and related health care systems.
The emphasis that official German documents make on the virtuously cooperative attitude between the *Bund* and the *Länder*, and which has normally been referred to when not emphasized in doctrine,[43] risks being oversimplified compared to a much more varied reality. In particular, a distinction must be made between (health and non-health) actions to respond to the pandemic and health system reorganization strategies that take their cue and occasion from the pandemic emergency. While, with regard to pandemic actions, the positive quality of cooperation is all to be proven, and indeed the very German-federal experience induces greater caution in evaluations (the circumstance that in that system there lacked a rule similar to that of our mentioned Article 117 of Legislative Decree no. 112/1998, then hastily introduced after the first wave),[44] as for the reorganization there

[40] See, for all, provocatively, S. Kropp, *Zerreißprobe für den Flickenteppich? Der Deutsche Föderalismus in Zeiten von Covid-19*, in *VerfBlog*, 26 may 2020.

[41] Considering that "the market for IT providers for the public health service is basically structured at the level of the individual Länder and focused on small and medium-sized companies, but also on local start-ups" (*DARP*, 5.1.1.iii.).

[42] For the related data, see *Tagesspiegel background*, 14 february 2023.

[43] For a recent example, see the contributions collected in *I* Federalizing Process *europei*, cit., particularly those of E. Ceccherini, J. Woelk e F. Palermo (and bibliographical indications mainly from German and US scholarship).

[44] This refers to the well-known circumstance whereby, after a tendency to agree on responses during the first pandemic wave, strong tensions arose between the *Bund* and the *Länder*, which led to multiple amendments to the Federal In-

seems to be no doubt about the proven quality of the rules and practices of interinstitutional cooperation between the *Bund* and the *Länder*: even in these weeks, in which the radical nature of some of the German-federal *Krankenhausreform* proposals has given rise to a heated political and scholarly debate pitting some *Länder* and their political majorities (notably the Bavarian CSU and the Baden-Württemberg Green Federation)[45] against each other, which has also developed within the same *Land* (between the district authorities and the state government), and which has found a crucial issue in the survival of small hospitals (as well as the relationship with university hospitals), the prevailing opinion among commentators is that in the end the federal project will hold precisely because of the proven cooperative practice: the *Bundestreue*. In short, this cooperation could be the underlying glue in the negotiations aimed at specifying the amount of federal resources allocated to the reform and their consequences for the financing of insurance funds. In addition to this, with specific reference to the decisions made in the pandemic waves following the first by the Bund, it was correctly observed that this greater centralization was more apparent than real, since "the states made decisions by mutual agreement on everything".[46]
If from the more circumscribed perspective of centre-periphery relations, we then turn to an examination of the attitudes of comparative scholarship on the set of issues pertaining to the relationship between health and the pandemic, one cannot fail to be struck by the widespread propensity to search among the orientations of the different legal systems for confirmation of certain theses held generally and prior to the outbreak of the pandemic, rather than to take the opportunity to attempt a general reconstruction of the actual trends of a comparative public law of the pandemic.
This attitude is particularly evident in part of Italian doctrine, regarding both the impact of the decisions adopted following the pandemic on the system of sources of law, on the distribution of competencies between the centre and the periphery, on the structure of the form of government and especially on the relations between executive-government and legislative assemblies. Just consider the flood of ink spilled on the very wide use of the

fection Protection Act (adopted on the basis of the *Konkurrierende Gesetzgebung*), in particular to allow the Federal Minister to adopt orders for the entire territory in the event of a nationwide epidemic: on this point, for all see J. Woelk, *I sistemi federali*, cit., pp. 336 ff.

[45] See the news and the comments in *Tagesspiegel background*, 13, 14 e 16 February 2023.

[46] J. Woelk, *op. ult. cit*, p. 349. This author's conclusion according to which the pandemic response would have demonstrated the greater resilience of federal systems compared to those of a regional state type is not convincing (see also, in the same sense, the reflections of E. Ceccherini, *Sistemi policentrici e principio collaborativo nell'emergenza pandemica*, in *I* Federalizing Process *europei*, cit., 183 ff.; the author's considerations on the lack of horizontal cooperation between regions in the Italian experience, *ibid*., 203-204, should lead to more cautious evaluations): this is partly correct with reference to the German-federal experience, albeit with the clarifications made in the text, but it is not so for other federal systems, and the reason lies precisely in the long-standing and consubstantial assimilation of the unwritten constitutional principle of the *Bundestreue*. For a balanced approach, see M.G. Rozell, C. Wilcox, *Federalism in a Time of Plague. How Federal Systems Cope With Pandemic*, in *American Review of Public Administration*, 2020, Vol. 50 (6-7), 519 ff.

instrument of the Prime Ministerial Decree (as if it were an act unknown to our system),[47] or the insistent emphasis about the compression of the autonomy of sub-state entities (forgetting that the first effect of a pandemic is to require concerted decisions promoted at the supranational level, and therefore, at least tending to be oriented in the direction of enhancing the national level as the optimal venue for coordinating the fight against the spread of the contagion),[48] or to the centralization in the hands of the executives of key decisions by marginalizing the parliamentary role[49] (thus underestimating what comparative scholarship has always noted about the correlation between emergency situations and decision-making centralization.[50]

But there is more: sometimes there is a somewhat hasty assimilation in doctrine between autonomy and asymmetry:[51] the former pertains to the dignity of each spatiotemporally identified collective entity, the latter to the uniformity or otherwise of the relations between smaller and larger entities, and thus to the relations between smaller entities among themselves. If the emergency is related to a pandemic, *i.e.*, such that it involves rapid and severe contagion that can affect anyone anywhere, the argument of its unequal distribution loses merit, since, in the absence of shared rules on bans on circulation, the potential pervasiveness of the virus discounts asymmetries and differentiations.[52]

On another front, the scholarship seems to be finding it very difficult to acquire from the lessons of the pandemic[53] a heightened awareness regarding the links between human

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[47] And not a type of act that has been used as an alternative to the regulatory source for years now: see, for all, V. Di Porto, *La carica dei DPCM*, in *Osservatorio sulle fonti*, 2, 2016; R. Balduzzi, *Splendore e decadenza di una figura controversa: le fonti atipiche*, in *Jus*, 2-3/2020, 564 ff.

[48] Nor do such precautions apply only to the physical distancing and movement of persons. One thinks of Regulation (EU) 2022/123, the last part of which concerns the strengthening of the role of the European Medicines Agency in coordinating the responses of EU countries to shortages of medicines and medical devices in health emergencies. Not only would it be totally insufficient to leave this task to sub-state authorities, but national coordination is also perceived as inadequate (on the other hand, the same coordination at EU level risks being insufficient, so much so as to require a global authority: on this point, see the considerations of R. Balduzzi, *La liberalizzazione dei diritti di proprietà intellettuale sui vaccini. Profili costituzionali e internazionali*, in *Quaderni costituzionali*, 2/2022, 263 ff.). Obviously, it is a different matter to require that the exercise of coordination tasks at the national level be concretely carried out through recourse to forms and techniques of loyal cooperation: on this point, see what will be said in the conclusion.

[49] Evidence of this undeniable tendency can be found in the implementation of the German *DARP*, especially with regard to the achievement of the objectives of the *Digitale und tecknische Stärkung des Őffentlichen Gesundheitsdienstes*: see the data referred to in the article cited back, at note 78.

[50] Here, too, it is another thing to call, even forcefully, not only for compliance with the established principles of strict necessity, proportionality and temporariness of the measures adopted, but also for the careful monitoring of the same, in order to protect the rule of law and related fundamental rights: on this point, see the agreeable considerations of F. Balaguer Callejón, *Diritto dell'emergenza e pluralismo territoriale*, cit., 31 ff., 36 ff.

[51] See the well-argued paper of F. Palermo, *Principio di sistema o intralcio al decisore l'asimmetria territoriale alla prova dell'emergenza*, in *I* Federalizing Process *europei*, cit., 47 ff.

[52] This explains, among other things, the already noted strong sharing between the German federal *Länder* and the *Bund* of the rules concerning the fight against the pandemic in the second phase of the virus, as it is not otherwise possible to prevent the movement of people between one *Land* and another, given the federal nature of the type of State.

[53] Covid-19 is, according to the prevailing reconstruction, a zoonosis caused by a virus that has jumped species, favoured by deforestation, the increasing density of humans and animals and a complex of hygienic-environmental factors: on

health and animal health, as well as the connection between them and environmental health, which the One Health perspective has come to synthesize today.[54] Of this, there is still a lack of full perception among scholars, if it is true that even a recent meritorious effort devoted to so-called environmental constitutionalism (or environmental constitutional law) does not address this interaction.[55] Yet, the affirmation of the environment in the constitutional perspective, all the more so after the Italian constitutional revision (Constitutional Law No. 1 of Feb. 11, 2022,), which emphasizes the links between the environment and health, could finally be an opportunity to place side by side with the now well-established expression of constitutional health law (or health constitutionalism) that of environmental constitutionalism.[56]

3. UK: Man shall not live by Brexit alone ...

At this point in our examination, it may be appropriate to take a brief look at the legal order of the United Kingdom, with which the Italian model of the National Health Service has historically derived links and which, although it has not adopted a national plan similar to the recovery and resilience plans of European Union countries,[57] has been affected by significant public policy reform processes, including those in the health sector.
The starting point is the *National Health Service England* reform law passed in April 2022, the *Health and Care Act*. Considered by some commentators as the seal on the dismantling

this point, among the most recent contributions, see G.T. Keusch et al., *Pandemic origins and a One Health approach to preparedness and prevention: Solutions based on SARS-CoV-2 and other RNA viruses*, in *PNAS*, Vol. 119(42), 10 October 2022.

[54] See the papers collected in the no. 3/2022 of *Corti Supreme e Salute*.

[55] D. Amirante, *Costituzionalismo ambientale. Atlante giuridico per l'Antropocene*, Bologna, 2022.

[56] Contrarily, we have witnessed, over time, a gradual estrangement between the two perspectives of study and research, made emblematic by the circumstance that one and the same scholar has rarely specialised in both topics, and this has contributed to weakening the research perspectives on the nexus (and this helps to explain the relative 'indifference' between the two fields of study). On the other hand, the establishment at WHO-Europe level of the Pan-European Commission on Health and Sustainable Development (whose link, almost 35 years later, with the Brundtland Report on Sustainable Development is transparent) was of the opposite sign: the link between environment and health is already engraved in the very name of the Commission. The Final Report, together with the preparatory documents, confirm this impression and indeed reinforce it through the strong focus on the One Health perspective: for guidance, see R. Balduzzi, *La liberalizzazione dei diritti di proprietà intellettuale*, cit., 263 ff.

[57] The choice seems to be connected not only to the obvious circumstance that, following Brexit, the conditions that in the European Union led to the construction of the Next Generation EU mechanism (common debt redistributed according to the intensity of the impact of the pandemic on individual countries and the planning of measures to respond to it, with the creation of constraints on compliance with this planning for the disbursement of funds), but also to the British government's conviction that there were no reasons for a general overhaul of the health system (how much of this conviction contributed to the current very serious crisis of the National Health Service remains to be established: see the *Lancet* editorial of 28 January 2023, *The NHS is sick, but it is treatable*).

of the NHS,[58] the reform identifies the pandemic not as its own root cause but, at most, as a factor accelerating the processes of change already underway in the English health care system, the management of the pandemic having exacerbated some critical trends (in particular, the weakening of public services' offer and the transfer of public resources to private hospitals) that have already been characterizing the evolution of the English NHS for about three decades.[59]

At the basis of the reform there is the need to pursue stronger integration between the health and social sectors, sought through a re-composition of NHS governance in which, on the one hand, the territorial size of the planning and commissioning bodies for services (the new Integrated Care Systems-ICS) has been increased and, on the other, several functions previously centralized at the national level have been decentralized to these bodies. Such "re-composition" would see within the ICSs a stronger presence of local authorities and thus greater empowerment of them in planning care needs and commissioning services.[60] Crucial is the issue of the composition of the board of the ICSs, whereas, in this regard the law specifies, not without vagueness, that the choice of candidates to hold this office must not weaken the independence of the body due to possible conflicts of interest of the persons appointed:[61] it does not seem to be an exaggeration to locate here the junction of reform, given that the current arrangement has been considered too permeable to private interests and a contributory cause of the growing disaffection with the NHS as a whole.[62] Proponents of reform emphasize the change of criterion in the relationship

[58] See, for all, P. Roderick, A.M. Pollock, *Dismantling the National Health Service in England*, in *International Journal of Health Services*, 2022, vol. 52(4), 470 ff.

[59] See especially S. D. Player, *Taking Care of Business: Privileging Private Sector Hospitals During the Covid Crisis*, in *International Journal of Health Services*, 2021, vol. 51(3), 305 ff.

[60] The *ICS* are equipped with two main operational arms: the *Integrated Care Board* (*ICB*) and the *Integrated Care Partnership* (*ICP*). The former, in particular, constitutes a real (as we would say on the continent) 'body' with a collegiate structure, with functions of planning and commissioning of health and social care services *vis-à-vis* public and private service providers (the two main areas of provision are primary care, which is mainly the responsibility of general practitioners (GPs), and secondary care, which is the responsibility of hospitals, but other areas of provision, such as emergency services or mental health services, should not be overlooked). As for preventive services, following the Health and Social Care Act of 2012, these were separated from the NHS and reallocated between central and local authorities (this separation was strongly criticised at the time for weakening the capacity to respond to future epidemics: on this point, see P. Roderick, A.M. Pollock, *Dismantling the National Health Service*, cit., 472.

[61] *Health and Care Act 2022*, *Schedule* 1B, *Part* 1, § 4: "*The constitution must prohibit a person from appointing someone as a member ("the candidate") if they consider that the appointment could reasonably be regarded as undermining the independence of the health service because of the candidate's involvement with the private healthcare sector or otherwise*".

[62] The *ICP*s replaced the Clinical commissioning groups (CCGs), established in 2013, following the Health and Social Care Act of 2012. These entities performed the commissioning function on behalf of the NHS of health services now assumed by the ICSs: so-called 'clinically-led' bodies. "Over time, they have become less of an expression of the technical-professional world and have come under strong influence from the service providers (a 2015 survey by Unite Union, one of the most important British trade unions, revealed that more than a quarter of the members of the CCG boards had interests in private healthcare, as shareholders, directors or collaborators: see the data published in the newspaper *The Independent*: https://www.independent.co.uk/life-style/health-and-families/health-news/over-a-quarter-of-board-members-on-new-bodies-commissioning-nhs-care-have-links-to-the-private-health-sector-10109809.html). It should be added that while the CCGs were relatively small in size, such that they could increase the ability of local authorities

between commissioners and providers from the doctrine of "quasi-markets," consisting of a non-competitive, but cooperative, arrangement of the relevant relationships, and the centrality of the so-called "integrated care strategy",[63] corresponding to our social-health integration. However, it is not clear what incentives might prompt private NHS providers to prioritize system goals instead of their own particular interests, and the circumstance of being represented on the ICB board is not, in itself, a guarantee of the system,[64] nor is the circumstance "*that providers are part of the ICS – just as much as the ICB and ICP are – and as such they are being asked to take on wider responsibilities for the performance of the whole system*".

Not surprisingly, given these premises, critics of the reform use "service integration" as their polemical target, and one of the most argued dissenting voices recently wrote that "*The Health and Care Act 2022 cements the major realignment of the relations between the state and the public that has been a long time in the making. Parliament has stood back and handed over most decision-making and power to unaccountable entities who will decide what services will be provided. This outsourcing of control over large sums of public money will also increase the opportunities for corruption. Health services in England will come to resemble those in the United States, where the state has also opted out of health care organization and direct provision to become an outlier among the majority of advanced democracies, distinguishable by high costs, inequality, and injustice. With successive governments, think tanks, and the mainstream media repeatedly denying that the NHS is being privatized — and hiding behind "service integration" and the pandemic — these consequences are already becoming apparent. Public satisfaction with the NHS is at its lowest since 1997. Nevertheless, at the same time, the public still overwhelmingly supports its founding principles. This provides a promising basis for continuing the vital and sustained campaigns to rebuild the NHS in England*", and that "*in the future providers will be able to decide how and where services are provided*".[65]

Nor it is surprising that, in this context, the debate around the transformation of GPs' employment relationship from self-employed to employee has also been renewed.[66]

to exert influence over them, the large size of the ICSs would weaken accountability both upwards (too many for the centre to control them) and downwards (too large for local authorities other than the large ones to have any influence): see P. Roderick, A.M. Pollock, *Dismantling the National Health Service*, cit., 474.

[63] https://www.kingsfund.org.uk/publications/integrated-care-systems-explained.

[64] See the document mentioned at note 106, and particularly the following passage: "*NHS providers are already playing a critical role in the changes underway in many systems, contributing to and/or leading work at ICS level to plan and transform services and improve system performance, and collaborating with other local providers (including those from outside the NHS) at place and neighbourhood levels to redesign care pathways and deliver more integrated services for local people*".

[65] In this sense P. Roderick, A.M. Pollock, *op. cit.*, 475, 477.

[66] https://www.bmj.com/content/376/bmj.o406.

Some conclusions

It seems difficult, at the end of the preceding brief examination, to escape from a first conclusion: the pandemic has acted as a powerful factor triggering the rethinking and restructuring of the relationship between health protection and the organization of health services, and this has also been found to be true with respect to those systems in whose regard there is a tendency to emphasize continuity with pre-pandemic processes of change and for which, as in the British experience, the stimulus constituted by the National Recovery and Resilience Plans does not apply. Certainly, the rethinking is taking place along very different directions and priority lines, given the differences in the history and characters of national health systems and also in consideration of the right to health, and therefore it now seems to privilege the direction of a reorganization of the territorial sub-network (Italy), the strengthening of the link between *ville/hôpital/médico-social* (France), the digitalization and reorganization of the hospital network (Germany), and the integration of care services (United Kingdom).

Nor is it difficult to discern a common element, albeit through differentiated organizational paths and linguistic connotations: the construction of integrated health networks, so that health protection is not exhausted in the provision of only health responses and less than ever concentrated in the hospital response alone: epidemiological changes, the increase in frailty and chronicity, the push in the direction that, analysing the Italian experience, has been summarized in the reversal of the relationship between need and service, and that constitutes a common denominator of the Italian *Case della Comunità*, the reform of the French *EHPAD*s, the German-Federal *Medizinisch-Pflegerischen Versorgungszentren* and the English *Integrated Care Strategy*.

As well as constituting a common denominator there is a need for a clear and transparent relationship between the world of public health and the variegated world of private operators: each country on this point makes history on its own, due to its different health systems and therefore to the different role of private economic initiative in the socio-health field, but there is no doubt that only a strong ability to govern the enormous interests that are concentrated in the field of health[67] will make it possible to win the most difficult challenge, which is to strengthen the theory and practice of prevention,[68] in the sense made

[67] Also in this regard, the need for a strong capacity to govern the interests of the national health authorities is acute: a centre, in short, capable of coordinating not only administrative requirements, but above all ‘regional’ programmes and actions, of valorising good practices, of taking standards seriously without, however, considering them untouchable: a centre with these characteristics will also be able to integrate the private sector operating in health, without being captured by the logic of the latter and ensuring, as some national regulations require, special attention to the private *non-profit* sector.

[68] On this point, the approach to health, environmental and climate prevention adopted in Italy by Ministerial Decree No. 77/2022 (no. 14 of Annex 1), both since it is there (and it was not so obvious) and since it incorporates the best international doctrine on prevention. A profile to be explored in more depth could be that of the complete silence on

proper by Article 35 of the Charter of Nice, and thus to provide a different connotation to the meaning of the "production" of health services and health.

On one point, closely related moreover to that of prevention, the lesson of the pandemic does not yet seem to have been fully understood: increasingly, health issues, even from the perspective of *One Health*, are global health issues, and as such must be understood and studied.[69]

With reference to us, the comparative examination should induce additional attention with respect to General Practitioners, whose requalification and reorganization constituted one of the primary objectives of Law Decree No. 158/2012,[70] to the point of including, in the awareness of the fatigue and resistance that had previously always characterized attempts at reorganization, a specific clause, by virtue of which, if within six months the national collective agreements concerning contracted physicians were not adjusted, the Minister of Health would issue "provisions for the transitional implementation of the principles" of the reform.[71] Secondly, the crucial nature of socio-health integration should be addressed, because of its close connection with the reorganization of territorial healthcare[72] and the difficulties it has always encountered in our country.[73]

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the function of general practitioners on the subject of prevention: who better than the general practitioner to know and orientate in the *mare magnum* of disease and addiction prevention?

[69] See, on this point, A. Renda, C. del Giovane, C. Perarnaud, H. Vu, *Broader, smarter, fairer. A more ambitious agenda for global health*, Bruxelles, CEPS In-depth Analysis, January 2023, spec. 44 ff., on ten areas for improvement in the current governance of global health security. Interesting is also the *Report* of the Pan-European Commission on Health and Sustainable Development, *Drawing light from the pandemic. A new strategy for health and sustainable development*, september 2021 (on which see the considerations of R. Balduzzi, *La liberalizzazione dei diritti di proprietà intellettuale*, cit., 263 ff.).

[70] Including the health-related part included in Decree-Law No. 95/2012, converted into Law No. 135/2012, the so-called *spending review*, and its main implementing measure, *i.e.*, the abovementioned ministerial decree on hospital standards) of the healthcare system, in which the reshaping of hospital organisation and related spending was finally accompanied by the reorganisation of territorial healthcare and related spending, starting from its 'heart', that is general medicine.

[71] Article 1, paragraph 6, Law Decree No. 158/2012.

[72] This integrates, in the strict meaning of the word (*i.e.*, bring to fullness), two activities that, if considered and practised in isolation, run the risk of not achieving their specific end. On this notion, and the reasons for or against writing with or without a hyphen, see the contributions published in *Corti Supreme e Salute*, 2/2018, 245 ff.

[73] The first is strictly conceptual and it concerns the many facets of the notion (professional, management, horizontal between municipalities, vertical between municipalities and regions, 'community', *i.e.*, referring to Third Sector entities and organisations: see, for all, E. Rossi, *Il "sociosanitario": una scommessa incompiuta?*, in *Corti Supreme e Salute*, 2/2018, 249 ff.); the second one concerns the persistent partial absence, at least in a general way, of the instrument capable of providing the cognitive and conceptual basis for a real integration, *i.e.*, the definition and standardisation of the essential levels of social assistance, the so-called LIVEAS (after Article 1, paragraph 159, of Law No. 234 of 30 December 2021, falling under the essential levels of social benefits, LEPS and, today, after Article 1, paragraph 701-801 of Law No. 197 of 29 December 2022, renamed again as LEP: on this point, see G.M. Salerno, *Con il procedimento di determinazione dei LEP (e relativi costi e fabbisogni standard) la legge di bilancio riapre il cantiere dell'autonomia differenziata*, in *Federalismi*, 1/2023), whose declaratory statement has now been binding on practitioners and the relevant political-administrative bodies for almost two decades. For developments on this point, see R. Balduzzi, *La questione sanitaria e i conflitti di competenza nell'emergenza pandemica*, in N. Antonetti, A. Pajno (a cura di), *Stato e sistema delle autonomie dopo la pandemia*, cit., 47.

Next to the General Practitioner issue, there is no doubt that, even in our country,[74] the pandemic placed the relations between the centre and the territorial autonomies under tension, and a "strongly critical position immediately emerged: a strong re-centralization of public powers was called for, as territorial decentralization - especially on the side of the Regions - would be one of the main causes on which the fragility and insufficiency of the responses offered by the institutions could be blamed. In short, there should be a "counter-reform" to that of 2001, given the disappointing results, all the more so given what happened during the health pandemic".[75] From an opposite point of view, as sometimes happens in Italy, proposals for so-called "differentiated regionalism" have been recovered, so as to assign in the field of health protection legislative powers to the regions not limited by the fundamental principles of state laws.[76]

Both positions appear flawed by political-ideological bias.

The first position, because many of the polemics about the inadequacy of the constitutional rules of distribution of competences between the state and regions to ensure an effective contrast of the pandemic have been hasty or specious, since, as I have argued at length elsewhere and as constitutional jurisprudence has dryly sanctioned since Judgment no. 37 of 2021, the powers assigned to the centre, even following the constitutional revision of 2001, are there and it is a matter of wanting to make good use of them.[77] It is

[74] Guidance in A. Morrone, *Per la Repubblica delle autonomie dopo la pandemia, in Europa*, in *Le istituzioni del federalismo,* 2021, 29 ff.; more recently, see the essays collected in no. 3/2023 di *Federalismi*.

[75] In this sense the editorial by Giulio Salerno, in *Newsletter Issirfa*, December 2022.

[76] About the bill approved by the Council of Ministers on 2 February 2023 (*Disposizioni per l'attuazione dell'autonomia differenziata delle Regioni a statuto ordinario*), see the interview with Sandro Staiano, signed by D. Cerbone, which appeared in *Nagora.org*, 16 February 2023.

[77] For developments on this profile, see my *La questione sanitaria e i conflitti di competenza*, cit., 30 ff. The new Title V has certainly had a significant impact, in general terms, on the structure of the State-regions relations, but, in the healthcare field, its impact has been modest, if not absent: the entrusting of healthcare matters to the regions dates back to the Constituent Assembly and the new Title V has not modified its characteristic features, while the so-called regionalisation of healthcare dates back to Legislative Decree No. 502/1992, confirmed, in this respect, by Legislative Decree No. 517/1993, and 'completed' by Legislative Decree No. 229/1999, *i.e.*, all measures prior to 2001. These arguments have generally been opposed by the existence of twenty-one different health systems, which has been felt, especially in these three years of the pandemic, as intolerable. Regardless, the National Health Service is the complex of regional health services and bodies and institutions of national importance (*e.g.*, the *Istituto Superiore Sanità*, *Agenas*, *Aifa*, *Istituto nazionale migrazione e povertà*) and is unitary: the foresight of the constituents was in understanding that health services are indeed better organised and manageable by leaving room for autonomy to the regions, but within a unitary framework that allows health to be guaranteed by the Republic. In this regard, it is no coincidence that the only region that has wanted to depart from the model of the National Healthcare System has shown widespread weakness, despite the favourable conditions of economic and social wealth and the presence in the region of eighteen institutes for hospitalisation and scientific care (out of a national total of over fifty), and that the overall network of its services has shown glaring functional defects (on the most recent Lombardy healthcare reform, see my considerations in *Balduzzi: serve un vero cambio di mentalità e cultura*, in *Avvenire*, 31 December 2021, 8). A second objection is the following: with regionalisation, we have differently efficient healthcare in different regions, with different speeds and quality of services. Here the objection is not to Title V, understood as being responsible for an excessive devolution of competences to the regions, but to regionalisation itself. Perhaps it would be worth questioning the methodological correctness of comparing the quality of healthcare in the territories where everything is different, while the real comparison should be between different sectors (health, education, transport, social assistance, etc.) within the same region, in order to ve-

no coincidence that the most timely response to critics of regionalization lies in the set of regulatory provisions included in Legislative Decree 112/1998, which is, in an act that represents the most advanced tip, so far, of regionalist thrusts within the Italian legal system.[78]
The second position, that of the proponents of the so-called differentiated regionalism, appears, on the other hand, to be conditioned by the intention to modify not so much the state-region relationship, but the very core of the National Health Service: the intertwining of the demands for "total" autonomy (without the constraint of compliance with fundamental principles) on the sharing of health costs between the NHS and patients and those concerning the so-called integrative health funds would in fact allow individual regions to substantially derogate from the basic structure of the Italian NHS and one of its basic rules (according to which financing must be ensured by general taxation), thus provoking its de-structuring. It is not difficult to discern in the combination of substitute funds, interventions on co-payments, "softened" rules as to "intramural" private activity of doctors and other health professionals and the possibility to hire health care personnel with fewer constraints and to pay them on a "differentiated" basis, the shift to a "two-tier" system, in which the quality of services and performance rendered by the public component would inevitably be recessive compared to that achievable within the private sector. In short, at the basis of the proposals to extend the application of Article 116, paragraph 3 Constitution to the matter of health protection as well, there seems to be a propensity, not even too subdued, for the progressive privatization of the Italian NHS and thus the overcoming of the model of Law No. 833/1978.[79]
To conclude, tentatively, on the characters and adequacy of the Italian response to the pandemic with regard to the relationship between health protection and the (re)organization of health services, it can therefore be said that this is centred on the reorganization

rify whether regionalised health services are not, even in disadvantaged territories, the sector that comparatively works best. For an example of the current *vulgata*, which combines blatantly erroneous evaluations from a legal-constitutional point of view with actual factual misrepresentations, see C. Sartoretti, *La risposta francese all'emergenza sanitaria da Covid-19: Stato di diritto e Costituzione alla prova della pandemia*, in *this Journal*, 2/2020, 1638 (note 1).

[78] Article 117 of that Legislative Decree provides that, in the event of public health or hygiene emergencies affecting several regional areas, emergency measures, including the creation of reference or assistance centres and bodies, are the responsibility of the State. The following must also be considered, again within Legislative Decree No. 112/1998: Article 112, paragraph 3, letter g), insofar as it assigns to the state competence for 'the surveillance and control of epidemics and epidemics of national or international dimensions'; Article 118, paragraph 1, letter e), which imposes reporting obligations on the regions concerning, inter alia, the occurrence and spread of human or animal diseases; Article 115, paragraph 4, which assigns to the State the coordination of the activity of stockpiling medicines for non-recurring use, serums, vaccines and prophylactic aids; Article 126, which retains to the State the administrative functions regarding international prophylaxis. It therefore seems correct to conclude that, (at least) on the subject of health emergencies, with regard to the division of competences between the State and the regions, it does not seem possible to speak of a 'dualist and equal, therefore undecided' model for Italy (in this sense, instead, A. Morrone, *La "visione trascendente" dei Lea e la realtà del Ssn. Critica su processo e merito nelle sentt. nn. 197/2019 e 62/2020 della Corte costituzionale*, in *Corti Supreme e Salute*, 1/2020).

[79] See the essays collected in *Corti Supreme e Salute*, 1/2020, and also R. Balduzzi, *La questione sanitaria e i conflitti di competenza*, cit.; R. Balduzzi, D. Servetti, *Regionalismo differenziato*, cit.

of the territorial sub-network, intertwined with the strengthening of e-health and in particular telemedicine, and that its effectiveness will depend on the occurrence of a series of technical-financial, cultural and political assumptions, of which I refer in a paper of a few months ago on CoSS, whose examination was the main subject of the study day held on April 26th 2023 at the Catholic University.

The considerations made so far may also be useful for finally overcoming the sterile approach in terms of the sustainability of health systems, normally employed for the purpose of dismantling universalist guarantees of health protection, already the subject, some years ago, of a famous critique by the so-called Romanov Commission,[80] taken up in these weeks by an editorial in Lancet, according to which the NHS is sick, yes, but curable.[81]

Each country will then be able to draw from the experience of other countries' useful elements to implement its own set-up of the relations between health protection: thus, the French experience of *débat public* could also be useful for Italian or English discussions, because a greater health citizenship may constitute an excellent antidote against the illiberal sirens and mystifications always lurking in the times of the infodemic. From this perspective, the increased knowledge of the health care system as an outcome of the pandemic could be something more than a noble wish, provided that the comparative reconnaissance of normative rules (of constitutional, ordinary and secondary regulatory sources) and their implementation and application is always accompanied by the consideration of factual situations and those pertaining to custom. *E.g.*, one cannot overlook, when thinking about measures to prevent and counteract pandemic contagion, the different fate of the "*Immuni App*" in Italy compared to that of the counterpart *Corona Warn App* in Germany, downloaded by more than half of the population.[82]

To respond to the question of whether the current pandemic, which has come to combine with personal and collective life contexts, has been transformed into a true syndemic,[83]

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[80] Commission on the Future of Health Care, *Building on Values. The Future of Health Care in Canada. Final Report*, National Library of Canada, 2003: There is no standard on how much a country should spend on health. The choice reflects each individual nation's history, values and priorities (...) The system is as sustainable as we want it to be.

[81] *The NHS is sick, but it is treatable*, in *Lancet*, 28 January 2023: "*In the debate about solutions, there are several unhelpful distractions. First, the Government's inclination is to believe that the current NHS model is unsustainable and needs radical change, with copayments and enhanced means-tested user contributions (…) This view is deeply wrong. With the right approach, the NHS is sustainable, and must maintain the principle of delivering free care at the point of need, which is the foundation for a just society. Second, that the NHS has a productivity problem; that it does not do enough with what it is given. This is to badly misunderstand the purpose of health care, which is not a factory for the sick, judged according to crude metrics of efficiency, but a service based on care, compassion, and quality. To continue to focus on doing comparatively more for comparatively less is dangerous and obviously harmful. Third, that the challenges faced by the NHS can be solved by drawing on a stronger private health sector. The UK's private sector workforce is mostly drawn from the same workforce that makes up the public sector. Robbing one to buttress another while fatally fracturing the health service makes no sense*".

[82] (On this point, see Robert Koch-Institut, *Infektionsketten digital unterbrechen mit der Corona-Warn-App*, 2020).

[83] According to the perspective first referred to, with regard to Covid-19, by R. Horton, *Offline: Covid-19 is not a pandemic*, in *Lancet*, 26 September 2020, vol. 389, 874, on which see the clarifications made by E. Mendenhall, *The Covid-19 syndemic is not global: context matters*, *ivi*, 28 November 2020, 1731. According to Horton, two categories of diseases interact

the answer may legitimately be different, but the premise for consciously answering it necessarily passes through a "national revival," according to the felicitous insight of Richard Horton.[84]

in the present pandemic: coronavirus infection (SARS-CoV-2) and a range of non-communicable diseases (NCDs), such as hypertension, obesity, diabetes, cardiovascular and chronic respiratory diseases, and cancer, which are present to a highly unequal degree in contexts of social and economic inequality. Syndemics would therefore be characterised by biological and social interactions between conditions and states, which increase a person's susceptibility to harm or worsen their health outcomes. According to Mendenhall, it is correct to apply the notion of a syndrome to Covid-19, as the current pandemic interacts with pre-existing health conditions and is determined by political, economic and social factors, but it is misleading to qualify it as a global syndrome: in some countries it has been a syndrome, but in others it has not (*e.g.*, New Zealand's policy approach in response to the crisis has been exemplary; many sub-Saharan African states have done better than the US, UK, Brazil and India). In the US, Covid-19 was a syndrome because pre-existing conditions such as hypertension, diabetes, respiratory ailments, systemic racism, distrust of science and leadership, and a fragmented healthcare system facilitated the spread of and interacted with the virus.

[84] "*Nothing less than national revival is needed*": in this sense, R. Horton, *Offline*, cit. (see *retro*, note 116).