The Biden Administration's activity on health matters and some international law obligations

by Gianpaolo Maria Ruotolo

Abstract: *L'attività dell'amministrazione Biden in materia di salute e alcune obbligazioni internazionali* - The paper analyses the latest practice of the United States relating to global health issues. It focuses on the US approach during the ongoing negotiations for the Pandemic Agreement under the auspices of the World Health Organisation and its relationships with the multilateral trading system. It also focuses on the impact on the right to health of the Executive order on artificial intelligence.

Keywords: United States; International law; World Health Organization; International Health Regulation; Pandemic Agreement; Global health, Artificial intelligence.

1. Prologue

This paper follows a previous one published two years ago on DPCE *on line* in which I analysed, in the perspective of international law, latest US practice in the field of international relations dealing with health protection.[1]

Then I recorded a clear reversal, by the Biden administration, of the trend of the Trump administration that preceded it, in the sense of a greater multilateralist attitude and a higher awareness of international commitments binding the United States on global health protection, and the return of the same Country within the members of the World Health Organization, in which it is nowadays one of the promoters of the Pandemic Agreement.

The practice of the last two years does not show significant changes in this general trend, if compared to what has already been highlighted. Here, therefore, I highlight some new elements of practice that are to be added to the context I already outlined.

So I'll proceed with a brief account of the approach of the administration chaired by Biden with regard to the protection of the health of American citizens in the domestic forum, read in an international law perspective, and then I'll go further on to deal with the international relevant elements of the latest US practice, mostly focusing on the ongoing

[1] G.M. Ruotolo, *US and WHO. President Biden and the Restoration of Ties with the World Health Organization: a new level of confidence?*, in *DPCE Online*, Special Issue, 1, 2023, 139 ss.

DPCE online
ISSN: 2037-6677

negotiations for the Pandemic Agreement and some health issues of the Biden's executive order on artificial intelligence.

2. The domestic approach: the influence of international law

During the last two years of Joe Biden's Presidency, American legislation in the field of public health expanded.

In the last stint of his presidential mandate, Joe Biden aimed to extending the access to public healthcare in order to grant a larger sanitary coverage, to simplify the complex bureaucracy that characterizes it and cut the costs of drugs prescription.[2]

Obviously, the main initiatives in the field of public health promoted by the Biden's administration are a response to Covid-19, such as a vaccination campaign and the initiatives concerning mental health disorders provoked by pandemic. Biden's administration also reinforced the Patient Protection and Affordable Care Act (PPACA)[3] with the purpose of making healthcare more equitable by providing more subsidies to the American population.

This approach seems to be compatible with at least some of the international obligations weighing on the USA for global health protection, which are nowadays not limited only to the international verge and the treatment of foreigners, but which also apply, as minimum standards, to the treatment of citizens.[4]

Even though there's no global consensus on what global health is, we can define it as «an area for study, research, and practice that places a priority on improving health and achieving equity in health for all people worldwide. Global health emphasizes transnational health issues, determinants, and solutions; involves many disciplines within and beyond the health sciences and promotes interdisciplinary collaboration; and is a synthesis of population based prevention with individual-level clinical care».[5]

[2] See J. Silberner, *How Joe Biden plans to heal American healthcare*, in *BMJ*, 2021, 372 ss.
[3] Also known as Affordable Care Act of, colloquially, as Obamacare, it is a U.S. federal statute enacted by the 111th United States Congress and signed into law by President Barack Obama on March 23, 2010. Together with the Health Care and Education Reconciliation Act of 2010 amendment, it represents the U.S. healthcare system's most significant regulatory overhaul and expansion of coverage since the enactment of Medicare and Medicaid in 1965. See E. Jokley, *Obamacare Has Become Even More Popular Over Biden's Presidency* at https://pro.morningconsult.com/analysis/obamacare-polling-popularity. See also https://www.whitehouse.gov/briefing-room/statements-releases/2023/12/30/fact-sheet-biden-%E2%81%A0harris-administration-releases-global-health-security-partnerships-annual-progress-report-demonstrating-results-from-united-states-investments/.
[4] "International Legal Framework Governing Public Health Emergencies". A.L. Taylor, *Global Health Law: International Law and Public Health Policy*, in *Int. Enc. Pub. Health* 268 (2017).
[5] J.P. Koplan, T.C. Bond, M.H. Merson MH, *et al.*, *Towards a common definition of global health*, in *Lancet*, 2009, 373 ss; M. Salm, M. Ali, M. Minihane *et al.*, *Defining global health: findings from a systematic review and thematic analysis of the literature*, in *BMJ Glob. Health* 2592 (2021).

It finds its basic international law sources in non-binding art. 25 of the Universal Declaration of Human Rights («Everyone has the right to a standard of living adequate for the health and well - being of himself and of his family»), and in binding ones, in art. 12 of the International Covenant on Economic, Social and Cultural Rights («The States Parties to the present Covenant recognize the right of everyone to the enjoyment of highest attainable standard of physical and mental health», on which The UN Committee on Economic, Social and Cultural Rights issued a General Comment),[6] in article 5 (e) (iv) of the International Convention on the Elimination of All Forms of Racial Discrimination of 1965, in articles 11.1 (f) and 12 of the Convention on the Elimination of All Forms of Discrimination against Women of 1979 and in article 24 of the Convention on the Rights of the Child of 1989.[7]

It seems that Biden's administration is aware that health and its protection are limits to the exercise of absolute State discretion and sovereignty, in all its emanations, in the sense that States are bound by international law both positive and negative obligations which, on the one hand, prohibit them to carry out behaviours that can massively threaten the health of the people who are located in their territory and, on the other, require them to organize their own domestic systems in order to guarantee some basic standards.

International right to health, indeed, imposes on States three different kinds of obligations: obligations to respect, obligations to protect and obligations to fulfil the right to health itself; these include preventing discrimination in access or delivery of care, refraining from limitations to contraceptive access or family planning, reducing environmental pollution, restricting coercive and/or harmful culturally-based medical practices.

So, Biden's administration seems aware that human rights-based approach to health imposes to provide strategies and solutions to help/urge/force political entities to help people enjoy the right to health and to develop a human rights-based health policy context.

[6] General comment No. 14, *The Right to the Highest Attainable Standard of Health*, doc. E/C.12/2000/4, 11 august 2000.

[7] Several regional human rights instruments also recognize the right to health, such as the European Social Charter of 1961 as revised (art. 11), the African Charter on Human and Peoples' Rights of 1981 (art. 16) and the Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights of 1988 (art. 10). The right to health has been proclaimed by the Commission on Human Rights, as well as in the Vienna Declaration and Programme of Action of 1993 and other international instruments. As per Europe, no explicit provision on health is contained in the European Convention on Human Rights, but the European Court of Human Rights has included the same right in the context of the right to life (art. 2), and the EU Charter of Fundamental Rights art. 35 (Health Protection) reminds that «Everyone has the right to access preventive health care and to obtain medical treatment under the conditions established by national legislation and practices. A high level of human health protection is guaranteed in the definition and implementation of all policies and activities of the Union».

DPCE online
ISSN: 2037-6677

3. The United States approach in the negotiations for the WHO Pandemic Agreement

As said and known, Biden's administration has restored the historical relationship between the United States and the World Health Organization (WHO), after Trump's withdrawal, and the United States has soon recovered, in the year 2023-2024, the status – held until before the Trump administration – of the largest economic contributor to the WHO.[8]

What's more, the role of the US within the WHO is nowadays particularly active, especially in consideration of the fact that it has a seat on its Executive Board until 2025.

As said, WHO Members reached a consensus to open a process to draft a treaty to prevent, detect, rapidly respond to, and recover to pandemics, the Pandemic Agreement.[9]

It was supposed to be adopted within 2024, with a vote on the definitive text at this year's WHO Assembly in May, nevertheless the negotiators – because of a lack of consensus on some articles of the draft – decided to prorogue the timeline for negotiations, with the expectation that the above mentioned draft will be voted during the WHO Assembly that will be held in 2025: despite the U.S. committed to complete negotiations and to hold a vote on the Treaty at this year's WHO meeting, they agreed with other member States in extending negotiations until next year, given the aforementioned lack of consensus.

In that context, the U.S. representative, co-led by the State Department and the Department of Health and Human Services, articulated goals aimed to ensuring that the forthcoming agreement enhances pandemic preparedness across all nations, facilitates mechanisms of laboratory data-sharing in a quicker and more transparent way, and supports equitable global access to pharmaceuticals, vaccines, and diagnostic tests during health emergencies. Biden Administration officials have stated they are optimistic about reaching consensus eventually, and that the «contours of the agreement are in place».[10]

As negotiations continue in a closed setting, information regarding U.S. positions on various components of the agreement remains limited and subject to modification. Generally, the American officials have granted support for the fundamental principles contained in the draft, among which are aspirational goals for enhancing pandemic preparedness capacities and promoting international cooperation.

Furthermore, U.S. representatives have agreed on the establishment of a Pathogen and Biological Sample (PABS) system, which will compel States to share pathogen samples and information, while also encouraging manufacturers of vaccines and other pandemic-related products to allocate a

[8] At http://open.who.int/2022-23/contributors/contributor.

[9] Revised draft of the negotiating text of the WHO Pandemic Agreement, 13 March 2024, available at https://apps.who.int/gb/inb/pdf_files/inb9/A_inb9_3-en.pdf. See I.R. Pavone, *Global Pandemics and International Law*, Oxon/New York, 2024, *passim*.

[10] See J. Michaud, J. Kates, A. Rouw, *The "Pandemic Agreement": What it is, What is isn't, and What it Could Mean for the U.S*, April 2024, available at https://www.kff.org/global-health-policy/issue-brief/the-pandemic-agreement-what-it-is-what-it-isnt-and-what-it-could-mean-for-the-u-s/.

designated percentage of their production for equitable distribution during public health emergencies.

On the other side, during the latest Intergovernmental Negotiating Body (INB) meetings, U.S. representatives articulated their opposition to the common but differentiated responsibilities (CBDR) approach, enshrined in art. 3, para. 4 of the Draft[11] and have argued against the establishment of a new funding mechanism for pandemic preparedness and response within the framework of the agreement.

On a more general way, U.S. representatives have expressed critical perspectives on *a)* the fact that the Pandemic Agreement would loosen US sovereignty, *b)* that some of the mechanisms it provides will burden on American taxpayers, and *c)* that the proposals to temporarily waive intellectual property rights (IP) for pandemic-related products would not effectively enhance equitable access during health emergencies and could potentially undermine the integrity of established IP systems.

About the fear of losing sovereignty there is to remind that art. 24, para. 3 of the current draft of the Pandemic Agreement[12] states that nothing in the WHO Pandemic Agreement shall be interpreted as providing the WHO Secretariat, including the WHO Director-General, any authority to direct, order, alter or otherwise prescribe the domestic laws or policies of any Party, or to mandate or otherwise impose any requirements that Parties take specific actions, such as ban or accept travellers, impose vaccination mandates or therapeutic or diagnostic measures, or implement lockdowns while, art. 3, para. 2 restates the sovereign right of States to adopt, legislate and implement legislation, within their jurisdiction, in accordance with the Charter of the United Nations and the general principles of international law, and their sovereign rights over their biological resources so, as it is easy to comprehend, the domestic fears about this specific issue seem mostly unfounded, also because, of course, the Agreement needs ratification by U.S. constitutional organs.[13]

Also the second issue seems mostly unfounded, if approached from a legal perspective: the draft foresees a coordinating financial mechanism in order to support the purposes of the treaty, that is principally based on voluntary financial contributions from States.

[11] «To achieve the objective of the WHO Pandemic Agreement and to implement its provisions, the Parties will be guided, inter alia, by the following: 1. full respect for the dignity, human rights and fundamental freedoms of all persons, and the enjoyment of the highest attainable standard of health of every human being; 2. the sovereign right of States to adopt, legislate and implement legislation, within their jurisdiction, in accordance with the Charter of the United Nations and the general principles of international law, and their sovereign rights over their biological resources; 3. equity as the goal and outcome of pandemic prevention, preparedness and response, ensuring the absence of unfair, avoidable or remediable differences among groups of people; 4. common but differentiated responsibilities and respective capabilities in pandemic prevention, preparedness, response and recovery of health systems».

[12] Revised draft of the negotiating text of the WHO Pandemic Agreement, doc. A/INB/9/3, 13 March 2024.

[13] The United States Constitution provides that the President «shall have power, by and with the advice and consent of the Senate, to make treaties, provided two-thirds of the Senators present concur» (Article II, section 2)

Moreover, the current draft, at art. 12, para. 6, lett. *c)* ("*Access and benefit sharing*"), provides that WHO shall conclude legally binding standard PABS contracts with manufacturers to provide voluntary non-monetary contributions, such as capacity-building activities, scientific and research collaborations, non-exclusive licensing agreements, arrangements for transfer of technology and know-how in line with Article 11, tiered pricing for relevant diagnostics, therapeutics or vaccines.[14]

4. The issue of IP rights between the Pandemic Agreement and TRIPs

About the protection of intellectual property rights, the fear expressed by US negotiators is that the Agreement may undermine IP rights by requiring companies to "give away" IP protections on pandemic-related products they develop, thereby reducing incentives to invest in research and development of such products.

It must be said that the issue of the relationship between IP rights and pandemic risks is not new and certainly did not arise for the first time with regard to Covid-19: already in 2007, for example, when a global spread of the H5N1 virus was feared, Indonesia, where the disease manifested for the first time, invoked some kind of "viral sovereignty" – which, according to this reading, would find its legal basis in art. 15, para. 1 of the Rio de Janeiro Convention on Biological Diversity (CBD), relating to the principle of State sovereignty over the genetic resources of its territory[15] – and refused to share with other Countries the biological material taken from infected patients, necessary for research on the virus and, therefore, for the development of a vaccine. This was made in order to denounce the unfairness of the international mechanism to fight pandemics, which provides for the right of pharmaceutical companies to free access to the genetic material of viruses, but doesn't impose them any obligation to guarantee free access to the remedies thus developed, which are instead patentable.

It must be remembered that the World Trade Organisation's Trade Related Intellectual Property Rights (TRIPs) system provides for a set of exceptions to the commercial exploitation of IP rights, aimed at facilitating research, development and access to inventions, including the exclusion of certain "objects" from patentability, and other exceptions to the rights deriving from patent ownership.[16]

In particular, art. 31 of the TRIPs Agreement ("*Other use without authorization of the right holder*") provides the possibility for a WTO Member

[14] S. Switzer, M. Eccleston-Turner, M. Rourke, A.R. Hampton, *Comments on Article 12: Pathogen Access and Benefit Sharing (PABS) of the "Revised Draft of the negotiating text of the WHO Pandemic Agreement, 13th March 2024, Geneva Graduate Institute WP*, at https://apps.who.int/gb/inb/pdf_files/inb9/A_inb9_3-en.pdf.

[15] Art. 15 ("*Access to Genetic Resources*"): «1. Recognizing the sovereign rights of States over their natural resources, the authority to determine access to genetic resources rests with the national governments and is subject to national legislation».

[16] See, the paper prepared jointly in 2020 by WTO, WIPO and WHO, *An integrated health, trade and IP approach to respond to the COVID-19 pandemic*, at Extract: An integrated health, trade and IP approach to respond to the COVID-19 pandemic.

State to establish, for one or more specific goods protected by a patent, a compulsory licensing regime, referring, by this expression, to a system of State licenses which permit the exploitation or the production of such goods *without the authorization of their owner*.

It should be highlighted that, in principle, art. 31, letter *f)* TRIPs provides for the *exclusively national* relevance of such compulsory licenses. We must also recall that, on 23rd January 2017, an amendment to the TRIPS Agreement entered into force: it is specifically aimed at ensuring that developing Countries have the tools to obtain and maintain access to generic pharmaceuticals at affordable prices. The road that led to the amendment was long: the first *consensus* of the States dates back to more than twenty years ago, to the *Doha declaration on the TRIPs agreement and public health* of 14th *November 2001*[17] which, in para. 6, recognized that «WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement», and therefore asked the competent WTO body (the Council on Trade-Related Aspects of Intellectual Property Rights)[18] «to find an expeditious solution to this problem and to report to the General Council before the end of 2002» (and for this reason today the resulting regulatory system is known as "paragraph six system").

Only two years later, WTO Members reached the decision to transform it into a permanent amendment to the TRIPs Agreement, which entered into force at the beginning of 2017: the amendment – also called for by the United Nations General Assembly at the *High-Level Meeting on Ending AIDS* in June 2016 (see the Political Declaration on HIV and AIDS: On the Fast- Track to Accelerate the Fight against HIV and to End the AIDS Epidemic by 2030 of 22 June 2016)[19] – balances, albeit only partially, the protection of intellectual property rights – necessary, as we mentioned, for pharmaceutical companies to promote research and development activities, certainly essential for the creation of new pharmaceuticals and therefore for the overall improvement of quality and duration of life – with the fundamental right to health, and demonstrates the provisions of the TRIPs Agreement are not, in principle, in conflict with the fundamental right to health protection.

The amendment, in order to protect public health, authorizes the *importation* , by developing and less developed Countries that are not able to produce them autonomously, of pharmaceuticals from third-Country producers under a compulsory licensing regime and, to this end, inserts a new art. 31 *bis* into the TRIPs Agreement, as well as an Annex and an Appendix,[20] all of which are aimed at derogating the territorial limit of compulsory licensing: the obligations imposed on exporting Countries pursuant to art. 31, letter *f)* mentioned above are in fact derogated just in order to allow each Member to export generic pharmaceuticals

[17] At https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm.
[18] At https://www.wto.org/english/tratop_e/trips_e/intel6_e.htm.
[19] At https://www.unaids.org/en/resources/documents/2016/2016-political-declaration-HIV-AIDS.
[20] At https://www.wto.org/english/docs_e/legal_e/31bis_trips_annex_e.htm.

manufactured under compulsory licensing adopted by it, to meet the needs of importing Countries.

So the provision operates as a legal basis for the adoption of licensing that allows Countries with limited or no production capacity at all to import generic medicines at affordable prices from Countries where pharmaceutical products are patented. Therefore, the multilateral trading system allows both the adoption of compulsory licenses for the production of pharmaceuticals and vaccines (which can be adopted in Countries that possess the necessary technologies) and the importation (by Countries that do not have such technologies) of them.

To these provisions refers art. 11, para. 4 ("*Transfer of technology and know-how*") of the Pandemic Agreement:

> The Parties that are WTO Members recognize that they have the right to use to the full, the flexibilities inherent in the TRIPS Agreement as reiterated in the Doha Declaration on the TRIPS Agreement and Public Health of 2001, which provide flexibility to protect public health including in future pandemics, and shall fully respect the use thereof by others.

The same article, at para. 3, states that

> During pandemics, in addition to the undertakings in paragraph 1 of this Article, each Party shall:
> (a) encourage holders of relevant patents regarding pandemic-related products, in particular those who received public funding, to forgo or otherwise charge reasonable royalties to developing country manufacturers for the use, during the pandemic, of their technology and know-how for the production of pandemic-related products; and
> (b) consider supporting, within the framework of relevant institutions, time-bound waivers of intellectual property rights to accelerate or scale up the manufacturing of pandemic-related products to the extent necessary to increase the availability and adequacy of affordable pandemic-related products.

The Draft, indeed, does not seem to require companies to give up any IP protections, but refers only to «time-bound waivers of intellectual property rights» in order to speed or scale up manufacturing of pandemic related products.

Let me also remind that its Preamble acknowledges that «intellectual property protection is important for the development of new medicines» and recognizes «the concerns about its dire effects on prices» and recalls that «the Agreement on Trade-Related Aspects of intellectual Property Rights (TRIPSs Agreement) does not, and should not, prevent Member States from taking measures to protect public health…».[21]

This language seems misleading, as it suggests that the primary issue with intellectual property is merely the elevated costs. This perspective contrasts sharply with the realities observed during the Covid-19 pandemic, where many individuals in the Global South were left without access to any

[21] See J. Michaud, J. Kates, A. Rouw, *The "Pandemic Agreement"*, *supra*, note 10.

vaccines due to IP owners' inability to meet demand. While IP rights are designed to encourage the development of new medicines and therapies, this incentive may fall short without substantial government funding: in fact, the U.S. invested billions over several decades in researching mRNA vaccines, producing them, and acquiring mRNA-based Covid-19 vaccines.

Latest U.S. practice, indeed, suggests an at least incomplete understanding of the need to address IP barriers to fight pandemics: the White House 2024 Global Health Security Strategy[22] declares to enhance prevention and response to infectious disease threats worldwide, without never addressing IP issues, and a fact sheet[23] from the Department of State and the Department of Health and Human Services released on 29th March 2024, while supporting equitable and timely access to vaccines and treatments for all, mentions IP as a «critical cornerstone of invention» without acknowledging it could also constitute a barrier to access.

In conclusion, we can observe that the Biden Administration supported the process that will lead to the adoption of the Pandemic Agreement, in spite of the several critiques raised by a certain part of the American political context and public opinion. Nevertheless, considering that the negotiating timeline has been prorogued until 2025, the role of the United State may change in the future, depending on the outcome of the Presidential election that will be held this fall.

5. Health related issues in Joe Biden's Executive order on Artificial Intelligence

On October 30th 2023 President Biden adopted an *executive order* on Artificial Intelligence (AI).[24] It is a very long (over 20,000 words) and complex document that, in a very broad way, refers to all automated predictive, perceptive or generative software capable of imitating certain human abilities; it stems from previous actions taken by the Biden Administration – including, in application of the approach that has dominated AI regulation up to now, the promotion, in July, of a series of "voluntary agreements"

[22] At https://www.whitehouse.gov/wp-content/uploads/2024/04/Global-Health-Security-Strategy-2024-1.pdf.

[23] At https://www.hhs.gov/about/news/2024/03/29/joint-update-department-state-department-health-human-services-negotiations-toward-pandemic-accord.html.

[24] *Executive Order on the Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence*, at https://www.whitehouse.gov/briefing-room/presidential-actions/2023/10/30/executive-order-on-the-safe-secure-and-trustworthy-development-and-use-of-artificial-intelligence/. Executive orders, as known, are administrative acts under the exclusive competence of the President, used to direct the behavior of federal government agencies, which, if adopted in execution of a delegation from Congress, can have the force of law and can be challenged for violation of the Constitution or of the delegation. In practice, they are used in cases of urgency or to adopt solutions or suggest interpretations that would be difficult to adopt through ordinary legislation; in matters of international relevance, they have also been used to execute international agreements *in domestic forum* (an example is the GATT 1947: see Footwear Distributors and Retailers v. US : "GATT itself became part of US law via executive orders in accordance with congressional delegation of power to the President").

signed by 15 large companies – and follows the project for an Artificial Intelligence Bill of Rights of 2022[25] and a previous *executive order* by President Trump in 2019 ("American AI Initiative").[26]

The new order, which cannot be fully analyzed here[27] (for a first reading see here), imposes on the developers of AI systems a set of rules based essentially on the *principle of transparency*[28], such as that of sharing with the Government the data on the safety of their systems *before* making them available to the public, based on the *Defense Production Act* of 1950,[29] a law associated with national security in contexts of armed conflict that was also used at the beginning of the Covid-19 pandemic to increase the national supplies of ventilators.

The order, from a regulatory perspective, covers eight areas: *a)* national security; *b)* individual privacy; *c)* justice and civil rights; *d)* consumer protection; *e)* labor and employment issues; *f)* AI innovation and U.S. competitiveness; *g)* international cooperation on AI; and *h)* AI expertise within the federal government, and, what's more for us, includes a special section on evaluating and promoting the ethical use of AI in healthcare.[30]

To ensure a safe and responsible deployment of AI in healthcare, public health, and human services, the order asks the Secretary of Health and Human Services (HHS), in consultation with the Secretaries of Defense and Veterans Affairs, to establish, by 27th January 2025, a HHS AI Task Force with the objective of developing a strategic plan focusing on policies and frameworks for the responsible use of AI technologies in healthcare that should include guidelines for predictive and generative AI technologies to enhance healthcare delivery while ensuring human oversight, implementing long-term safety protocols to monitor AI technologies' performance across diverse population groups, integrating equity considerations by utilizing disaggregated data to address biases in AI applications, embedding safety measures into the software development lifecycle to protect personal information, providing resources to help users safely implement AI in local healthcare settings, working with various health agencies to promote best practices for AI use, and identifying AI applications that enhance efficiency and satisfaction within healthcare workplaces.

HHS is asked to create a strategy for evaluating the quality of AI technologies in healthcare, including developing an AI assurance policy for pre-market assessment and post-market oversight and guarantee its compliance with non-discrimination laws. This includes providing technical

[25] "Making automated systems work for American people", at www.whitehouse.gov/ostp/ai-bill-of-rights.

[26] Executive order 13859 of February 2019, at https://trumpwhitehouse.archives.gov/ai/.

[27] For a first reading see here.

[28] On the uncertainty regarding the validity of such a "principle" at a customary level in the international legal order, see A. Bianchi, *On Power and Illusion: The Concept of Transparency in International Law*, in A. Bianchi, A. Peters (Eds.), *Transparency in International Law*, Oxford, 2013, 1 ss.

[29] 50 USC § 4501 *et seq*, at https://www.fema.gov/disaster/defense-production-act.

[30] In general see E. Santamaria Echverria, *Artificial Intelligence and the Right to Health*, in A. Quintavalla, J. Temperman (Eds.), *Artificial Intelligence and Human Rights*, Oxford, 2023, 388 ss.

assistance to healthcare providers regarding their obligations under these laws, issuing guidance on compliance issues as they arise, creation of an AI Safety Program.

Within a year the Order asks for an AI safety program to be established in collaboration with Patient Safety Organizations, in order to create a framework for identifying clinical errors linked to AI usage and analyse data from reported incidents to develop recommendations aimed at preventing harm caused by bias or discrimination.

These initiatives reflect a comprehensive approach to integrating AI into healthcare while prioritizing safety, equity, and compliance with existing laws.

The order was adopted, under the pressure[31] of the adoption of the EU Regulation 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonized rules on artificial intelligence, by the circumstance that China presented its *Global AI Governance Initiative* on 18 October 2023, and in the imminence of the Artificial Intelligence Safety Summit (AISS), the first international conference on artificial intelligence, convened on 1 and 2 November 2023 by the United Kingdom.

It all probably happened in the hope of limiting a particularly vivid revival of the so-called Brussels (or Beijing?) effect[32] but also demonstrates the Biden Administration's permeability to "suggestions" coming from other States and the international community.

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[31] In the same sense see L. Leffer, *Biden's Executive Order on AI Is a Good Start, Experts Say, but Not Enough*, in *Scientific American*, oct. 31, 2023.

[32] A. Bradford, *The Brussels Effect*, in 107 *Northwest. Univ. Law Review* 1 (2012).

DPCE online
ISSN: 2037-6677