

# Pharmaceutical policy in the Biden agenda

by Anna Ciammariconi

**Abstract:** *Politiche farmaceutiche nell'agenda Biden* - The article provides an analysis of the pharmaceutical policy under the Biden Administration. The focus is on Executive Orders and measures in some key areas such as: lowering prescription drug costs for Americans; strengthening Americans' access to health coverage; addressing reproductive health and distribution of abortion pills (a very relevant issue, especially after the US Supreme Court judgment which overruled the leading case *Roe versus Wade* of 1973).

**Keywords:** Pharmaceutical policy; US Government; Biden Presidency; Drug costs; Health coverage; Distribution of abortion pill

## 1. Introduction

This paper examines the pharmaceutical policy agenda of the U.S. Administration during President Biden's term, focusing on the regulations approved between 2021 and 2024. While this analysis does not specifically address the COVID-19 pandemic and the vaccination campaign, it is worth noting that these issues were central to Biden's political and pharmaceutical agenda. Within the scope of this examination, the Presidential agenda was robust, as demonstrated by a detailed analysis of the main executive orders, laws, and speeches delivered by President Biden throughout his mandate.

## 2. The main pharmaceutical policy areas

The primary objective of the pharmaceutical policy was to lower prescription drug costs. This issue has been a recurring priority for American Presidents, a concern justified by data. It is widely recognized that drug prices in the US are significantly higher compared to those in other countries.<sup>1</sup> The issue is directly related to American healthcare system, in which both public and private managements coexist, with a prevalence of the latter. This kind of system has huge consequences in several fields, including prices, strongly influenced by the market – in opposition to other areas where there is some direct or indirect Government control. The

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<sup>1</sup> For an analysis, see L. Simonetti, *Le nuove traiettorie geografiche dell'industria farmaceutica globale*, in *Sem. Studi e Ricerche di Geografia*, I, 2018, 79 ss. Even if dated, an useful synthesis is available in OECD Health Policy Studies, *Pharmaceutical Pricing Policy in a Global Market*, 2008.

evolution of the legal framework, increasingly characterized by public intervention – particularly through measures affecting public welfare programs such as Medicare and Medicaid – has not altered the fundamental nature of the system, which continues to maintain a predominantly private orientation, positioning itself among the so-called need-based welfare state systems.<sup>2</sup> In this kind of systems, assistance and protection is not guaranteed on a universal scale, but only to specific categories and subjects, after the assessment of the actual existence of the conditions of necessity. Health coverage is primarily provided through private insurance policies, while public coverage is granted to specific categories of people, i.e. people over the age of 65 and those with low incomes, or people with disabilities.<sup>3</sup>

As shown by recent paper,<sup>4</sup> the gap between US drug prices and those in other countries' has widened. These data confirm the trend observed in previous periods. The 2019 Medicine Price Index<sup>5</sup> records the prices of numerous medicines (both branded and generic) widely used across various countries and calculates the average price for each drug. The data collected confirms that in the United States the cost of medicines is much higher than elsewhere,<sup>6</sup> and medicines cost on average more than 306% more than the average price of 50 other countries around the world.<sup>7</sup> An eloquent example is the cost of insulin – a well-known drug for the treatment of diabetes – which in the United States costs five times more than the world average for drugs intended for the treatment of this disease.<sup>8</sup> This issue is closely linked to the role played by multinational pharmaceutical companies, which, in addition to exerting significant lobbying efforts, tend to adopt strategies and practices aimed at keeping a drug “evergreen”. This involves effectively preventing the loss of the exclusivity provided by the patent protection. The companies modify drug formulations, creating new versions that are similar to those already on the market and whose patents are nearing expiration.

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<sup>2</sup> See G. Esping Andersen, *The Three Worlds of Welfare Capitalism*, London, 1990.

<sup>3</sup> According to the OCSE data, in the last years there has been a tendentious decrease of the part of the population not covered by some sanitary insurance. However, the country still has one of the highest percentages of people – if compared with other OECD countries – who renounce medical treatments due to high costs, and the highest level of surrender of buying prescription drugs.

<sup>4</sup> The Authors are A.W. Mulchahym, D. Schwam, S.L. Lovejoy. Published in Feb. 2024 and available in open access on file:///Users/utente/Downloads/RAND\_RRA788-3%20(1).pdf.

<sup>5</sup> See <https://www.medbelle.com/medicine-price-index/>.

<sup>6</sup> For an accurate analysis see L. Simonetti, *Le nuove traiettorie geografiche dell'industria farmaceutica globale*, cit., 79 ss. Even if dated, an useful synthesis is available in OECD Health Policy Studies, *Pharmaceutical Pricing Policy in a Global Market*, 2008.

<sup>7</sup> D. Blumenthal, M.E. Miller, L. Gustafsson, *The U.S. Can Lower Drug Prices Without Sacrificing Innovation*, in *Harvard Business Reviews*, available at <https://hbr.org/2021/10/the-u-s-can-lower-drug-prices-without-sacrificing-innovation>.

<sup>8</sup> The topic in question is not at all disjointed, then, from the role played by drug multinational company, which, in addition to exercising a profound lobbying action, are oriented towards adopting measures and practices in order to make a drug evergreen, i.e. substantially avoiding the loss of the plus due to the patent coverage: the formulations are modified, effectively creating analogous drugs (to those already on the market and about to expire of the relative patent), very expensive (thanks to the patent coverage) preventing the substantial impracticability the diffusion of generic drugs.

These new versions, still protected by patents, are priced high, effectively hindering the availability and widespread use of generic alternatives.

Other key areas of the pharmaceutical policy within Biden agenda include strengthening Americans' access to affordable, quality health coverage and the distribution policy for the abortion pill in authorized pharmacies.<sup>9</sup> On the issue of insurance coverage, President Biden follows the policies adopted by previous Presidents and, in particular, by President Obama, whose reform (the Affordable Care Act) provided the "individual mandate", i.e. the obligation for insurance companies to grant the stipulation of insurance coverage – a minimum essential coverage – to anyone who requested them (and regardless of their clinical picture).<sup>10</sup> The latter measure – the distribution of the abortion pills – is a response to the effects and consequences of the US Supreme Court's June 24th, 2022 decision, which overturned the 1973 *Roe v. Wade* ruling that had recognized the federal constitutional right to abortion in the United States. The decision has generated a strong echo in the public opinion and the adoption of anti-abortion measures by some States. Recently (April 21, 2023), the Supreme Court returned to this issue interrupting the restrictions imposed on the use of the abortion pill. A decision that moves in the same direction of the President Biden policies, opposed to the ban on the abortion pill access.<sup>11</sup>

Two of the above-mentioned issues (i.e. the policy to lowering drug prices and the strengthening Americans' access to health coverage), have been recurring topics on the US Administrations' agenda. In fact, even a brief review of the measures adopted by various American Presidents reveals numerous policies addressing these concerns. As already mentioned, the "Obamacare" (presidential mandate 2009-2017), was aimed at increasing healthcare coverage and at expanding the insurance obligation for large parts of the population. Instead, President Trump (in office from 2017 to 2021), despite his efforts to repeal and replace Obamacare, prioritized the need to reduce drug prices.<sup>12</sup> Some years before, the measures approved by President G.W. Bush (in office from 2001 to 2009) were aimed at expanding Medicare coverage to include more beneficiaries. Similarly, during President Clinton's administration (1993-2001), the Health Security Plan was aimed at providing universal health coverage. Regarding the objective of reducing drug prices, it is necessary to clarify that this goal encompasses a wide range of products, including prescription drugs, medications covered by federal programs (such as Medicare and Medicaid), and other types of drugs.

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<sup>9</sup> For informations, see <https://www.whitehouse.gov/briefing-room/statements-releases/2022/08/03/fact-sheet-president-biden-issues-executive-order-at-the-first-meeting-of-the-task-force-on-reproductive-healthcare-access-2/>.

<sup>10</sup> See E. Jorio, *La riforma sanitaria di Barack H. Obama*, in [www.federalismi.it](http://www.federalismi.it), 17/2009, 1 ss.

<sup>11</sup> See [https://www.supremecourt.gov/opinions/22pdf/22a901\\_3d9g.pdf](https://www.supremecourt.gov/opinions/22pdf/22a901_3d9g.pdf) and A. Howe, *Court allows abortion pill to remain widely available while appeals proceed*, in <https://www.scotusblog.com/2023/04/court-allows-abortion-pill-to-remain-widely-available-while-appeals-proceed/>.

<sup>12</sup> See A. Ciammariconi, *Pharmaceutical Policy after The First Two Years of President Trump*, in G.F. Ferrari (ed.), *The American Presidency under Trump*, The Hague, 2020, 151 ss.

## 2.1 Lowering prescription drug costs for Americans

Focusing on one of the main pillars of Biden's pharmaceutical policy agenda – considering the executive orders adopted by the President – the EO 14087 (signed on October 14th, 2022) on lowering prescription drug costs for Americans stands out among the others.

In its Preamble, Biden underlines that “Americans pay two to three times as much as people in other countries for prescription drugs”,<sup>13</sup> and in light of the above, the President thought it was necessary to generate new payment and delivery models aimed at lowering the prices of prescription drugs, focusing on models that can be tested through a specific Center for Medicare and Medicaid Services (CMS).<sup>14</sup> It is important to underline that this EO was not an impromptu measure, adopted just before the mid-term elections. In fact, a year before, on July 9th, 2021, Biden signed the EO 14036 on Promoting Competition in the American Economy, including several measures intended to improve competition, to increase wages, and to reduce prices for prescription drugs, among other goods and services.<sup>15</sup> This executive order included a detailed outline of the framework dedicated to achieving these goals. It specified the necessary actions aimed at reducing prices, improving access to prescription drugs and biologics, and simultaneously continuing to promote competition for generic drugs and biosimilars by facilitating their approval.<sup>16</sup> Moreover, the Food and Drugs Commissioner would have cooperated with the States and Indian Tribes to reduce the cost of covered products “without imposing additional risk to public health and safety”.<sup>17</sup>

It must not be omitted that the goal of intervening on the drugs prices should be read also as an attempt to contain the phenomenon of US residents' “pharma tourism”, especially in the nearest countries like Mexico, where drugs costs are cheaper. The impact of intellectual property rights protection regulations is also significant,<sup>18</sup> as they can inhibit or delay competition from generic drugs for many years, effectively denying Americans access to more affordable medications.

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<sup>13</sup> It's impressive that “Nearly 3 in 10 American adults who take prescription drugs say that they have skipped doses, cut pills in half, or not filled prescriptions due to cost”. For a comparison between the USA and other Countries, see R. Tikkanen, M.K. Abrams, *U.S. Health Care from a Global Perspective, 2019: Higher Spending, Worse Outcomes?*, Commonwealth Fund, Jan. 2020.

<sup>14</sup> For more details, see <https://innovation.cms.gov/>.

<sup>15</sup> On this EO, Biden signaled that “Americans are paying too much for prescription drugs and healthcare services—far more than the prices paid in other countries”. Data available on [www.rand.org/content/dam/rand/pubs/research\\_reports/RR2900/RR2956/RAND\\_RR2956.pdf](http://www.rand.org/content/dam/rand/pubs/research_reports/RR2900/RR2956/RAND_RR2956.pdf).

<sup>16</sup> See, in particular, par. (v) of the EO. This is possible by making generic drug and biosimilar approval more transparent; supporting biosimilar product adoption; identifying any efforts to impede biosimilar and generic drug competition. See par. (v), lett. (A), (B), (C), (D).

<sup>17</sup> See EO, par. (q).

<sup>18</sup> See Agreement on Trade-Related Aspects on Intellectual Property Rights (Trips Agreement), available at [www.wto.org/english/docs\\_e/legal\\_e/27-trips\\_01\\_e.htm](http://www.wto.org/english/docs_e/legal_e/27-trips_01_e.htm).

In the EO, the President affirmed that an important objective of the Administration was “to support aggressive legislative reforms that would lower prescription drug prices, including by allowing Medicare to negotiate drug prices, by imposing inflation caps, and through other related reforms. It is further the policy of [the] Administration to support the enactment of a public health insurance option”. In accordance with what was established in the EO, the Department of Health and Human Services (HHS) submitted a Report<sup>19</sup> to the White House Competition Council calling for legislative and administrative actions to lower drug prices. Focusing on the key points of the Report, there are three guiding principles: supporting drug price negotiations with manufacturers and stopping unreasonable price increases to ensure access to medications that could improve health for all Americans; enhancing and promoting competition throughout the prescription drug industry; and fostering public and private research while ensuring that market incentives are geared towards the discovery of valuable and accessible new treatments, rather than market manipulation.

In line with these efforts to reduce drug costs, it is worth noting that on August 16th, 2022, President Biden signed into law Public Law 117–169, known as the Inflation Reduction Act of 2022 (IRA), which included significant measures to protect Medicare beneficiaries from high drug costs.<sup>20</sup> Following the approval of the IRA, the Department of Health and Human Services took measures to implement its provisions and reduce healthcare costs for Americans. The 2022 IRA is a comprehensive and multifaceted law that, directly or indirectly, addresses pharmaceutical policy issues. Notably, it grants Medicare the authority to negotiate the prices of selected high-cost prescription drugs, particularly benefiting Medicare Part D<sup>21</sup> recipients).<sup>22</sup>

During the second half of presidential mandate, an important measure in the Biden agenda was the implementation of the law to lower the price of prescription drugs. And in this way, the CMS and HHS engaged in

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<sup>19</sup> The text of the Report is available at <https://aspe.hhs.gov/sites/default/files/2021-09/Competition%20EO%2045-Day%20Drug%20Pricing%20Report%209-8-2021.pdf>.

<sup>20</sup> Particularly, “by phasing in a cap for out-of-pocket costs at the pharmacy and establishing a \$35 monthly cap per prescription for insulin covered by a Medicare prescription drug plan and insulin delivered through traditional pumps”. Moreover, “Medicare beneficiaries with prescription drug coverage will pay \$0 out of pocket for recommended adult vaccines (including the shingles vaccine). IRA will also require certain companies to pay Medicare rebates if they increase the prices of drugs used by Medicare beneficiaries faster than the rate of inflation. In addition, the Secretary of HHS ... will be able to negotiate prices for selected high-cost prescription drugs for Medicare beneficiaries for the first time ever”.

<sup>21</sup> Part D was enacted as part of Medicare Modernization Act of 2003 and went into effect on January 1<sup>st</sup>, 2006. It is an US federal-government program to help Medicare beneficiaries pay for self-administered prescription drugs.

<sup>22</sup> Subtitle B – known as “Lowering Prices through Drug Prices Negotiation” – includes detailed measures on a Drug Price Negotiation Program to Lower Prices for certain High-Priced single-source drugs. The program is structured in a sequence of steps. In order to establish a drug price negotiation program, the Secretary publishes a list of selected drugs; and then enters into agreements with manufacturers of the selected drugs; this happens with a defined timing.

negotiations/agreements<sup>23</sup> with drug companies to secure lower drug prices for the first 10 drugs selected under the Medicare drug price negotiation program.<sup>24</sup>

Finally, two recent important milestones (during the years 2023-2024) in the Biden pharmaceutical agenda can be mentioned, especially on issue of lowering drug prices.

On the one side, actions aimed at stopping anticompetitive practices by dominant corporations in health care markets and incentivizing competition are envisaged, by specific measures and particular attention to increasing ownership transparency.<sup>25</sup> On the other, the lowering drug prices of a drugs' list<sup>26</sup> and the new prices will be effective in the 2026, for people with Medicare Part D prescription drug coverage.

## 2.2 Strengthening Americans' access to affordable, quality health coverage

The second pillar of the pharmaceutical policy of the Biden agenda – in continuity with Obamacare – dealt with the access to affordable, quality health coverage for the Americans people.<sup>27</sup> As already mentioned, this has been a recurring issue on the agenda of the US Presidents. In fact, it should be remembered that the US healthcare system is set up in a purely private sense with a central function played by the insurance system and private

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<sup>23</sup> Available on <https://www.cms.gov/files/document/inflation-reduction-act-manufacturer-agreement-template.pdf>.

<sup>24</sup> They held meetings and, for some of the selected drugs, this process of exchanging revised offers and counteroffers resulted in CMS and the pharmaceutical company reaching an agreement on a negotiated price for the drug. In some cases, CMS accepted a revised counteroffer proposed by the drug company. For the other selected drugs, CMS sent a final written offer to those drug companies and the drug company accepted CMS's offer on or before the statutory deadline. See the documents available on <https://www.cms.gov/inflation-reduction-act-and-medicare/medicare-drug-price-negotiation>.

<sup>25</sup> For a synthesis, see <https://www.whitehouse.gov/briefing-room/statements-releases/2023/12/07/fact-sheet-biden-harris-administration-announces-new-actions-to-lower-health-care-and-prescription-drug-costs-by-promoting-competition/>.

<sup>26</sup> Available at <https://www.whitehouse.gov/briefing-room/statements-releases/2024/08/15/fact-sheet-biden-harris-administration-announces-new-lower-prices-for-first-ten-drugs-selected-for-medicare-price-negotiation-to-lower-costs-for-millions-of-americans/>.

<sup>27</sup> The ACA, among the other measures, aimed to expand the portion of the population covered by public insurance.



programs – a system that coexists with public welfare program, i.e. Medicare<sup>28</sup> and Medicaid.<sup>29</sup>

Focusing on the measures adopted by President Biden in this area, executive order 14070, titled “Continuing To Strengthen Americans’ Access to Affordable, Quality Health Coverage” played a central role.

This EO was built on the previous EO 14009, signed in January 2021, titled Strengthening Medicaid and the Affordable Care Act. It served as a natural continuation of the efforts outlined in the earlier order, which aimed to protect and strengthen Medicaid and the Affordable Care Act (ACA) while making high-quality healthcare accessible and affordable for every American.

In line with EO 14009, several federal agencies have implemented numerous actions to protect and strengthen Medicaid and the ACA. These policies were based on the fact that many Americans did not have insurance yet and were not eligible for one of the federal public programs. In detail, it is estimated that over 30 million Americans remain uninsured, preventing many from obtaining necessary health services and treatment. In line with this view, two EOs of the Trump Era were revoked.<sup>30</sup> It is not superfluous to remember that one of the main Trump administration goals was to repeal the principles of Obamacare and that one goal of these EOs (n. 13813) was based on the idea “that the Patient Protection and Affordable Care Act (PPACA) [had] severely limited the choice of healthcare options available to many Americans and [had] produced large premium increases in many State individual markets for health insurance; the fundamental idea of this regulations was to continue to focus on promoting competition in healthcare markets and limiting excessive consolidation throughout the healthcare system”.

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<sup>28</sup> Medicare is a national social insurance program, under the direct management of the federal government and designed with the main purpose of guaranteeing coverage for medical expenses to the least protected categories of the population. The program is for people over the age of 65, and those with a disability or end-stage renal disease (ESRD) requiring dialysis or a transplant. The “Original Medicare” is articulated in Medicare A and Medicare B: the first – inherent in hospital insurance – covers the costs related to hospitalization for patients from 65 years of age, regardless of their income; the second – linked to medical insurance – has the purpose of ensuring coverage of the expenses deriving from the services performed by doctors and health personnel; Medicare B requires payment of a monthly premium. In 2003, Congress approved the Medicare Prescription Drug Improvement and Modernization Act, which introduced Medicare Part D, relating to insurance coverage for prescription drugs. Medicare Part D is managed by private insurance companies operating within the national regulatory framework and, therefore, is likely to be exposed to differences between States. Medicare Part C, also known as Medicare Advantage, completes the framework and its plans generally contribute to the payment of some categories of prescription drugs.

<sup>29</sup> Medicaid is a program funded by both federal and state governments. The program is extended to low-income families, pregnant women, people with disabilities (regardless of age) and those in need of long-term medical care now. The program is implemented differently in each State, although there are federal guidelines to apply. Typically, patients are not required to contribute to the cost of medical expenses, although patient contributions may sometimes be required.

<sup>30</sup> EO 13765, Jan 20, 2017 – *Minimizing the Economic Burden of the Patient Protection and Affordable Care Act Pending Repeal* – and EO 13813, Oct 12, 2017 – *Promoting Healthcare Choice and Competition Across the United States*.

President Biden followed the path set by the Obama Administration, and during the first half of his term, one of the most significant measures adopted was the signing of the American Rescue Plan Act of 2021 (Public Law 117-2) on March 11, 2021, which further strengthened Medicaid and the ACA in numerous ways, “including by making ACA coverage more affordable for 9 million Americans through enhanced ACA subsidies, incentivizing States to adopt the ACA’s Medicaid expansion, making it easier for States to extend postpartum Medicaid coverage, establishing new options for States to establish mobile crisis intervention services teams to help provide services to Medicaid beneficiaries experiencing a behavioral health crisis, and increasing Medicaid funding for home- and community-based services to strengthen and expand access to services for millions of seniors and people with disabilities who need care as well as to help States strengthen their programs”.

Referring back to the aforementioned executive order, specifically Section 2 of EO 14070 – which was closely linked to the previous EO signed on January 28, 2021 – it is noted that, in addition to implementing the directives outlined in EO 14009, agencies responsible for Americans’ access to health coverage had to review actions to find ways to further expand the availability of affordable health coverage, enhance the quality of coverage, strengthen benefits, and assist more Americans in enrolling in quality health plans. The heads of these agencies were required to review policies or practices that facilitated consumer enrollment and retention of coverage, as well as those that strengthened benefits and enhanced access to healthcare providers. Additionally, they had to assess policies aimed at improving the comprehensiveness of coverage, protecting consumers from low-quality plans, and reducing the burden of medical debt on households.

In the second half of his term, President Biden focused his policy on cracking down on so-called “junk insurance”. In this area, Biden identified several key actions, including limiting short-term plans to 3 or 4 months and requiring clear disclosure of benefit limitations. This means that these plans must explicitly inform consumers that they offer a defined benefit rather than providing comprehensive coverage.

### 2.3 Abortion pills after US Supreme Court decision overturning Roe versus Wade

In the final part of his term, President Biden’s pharmaceutical policy agenda was significantly influenced by the consequences related to the Supreme Court’s decision *Dobbs v. Jackson Women’s Health Organization* on June 24, 2022. In this ruling, the Court, by a majority of 6 to 3, declared that the right to abortion is not protected by the Federal Constitution.<sup>31</sup>

This decision therefore overturned a “historic precedent” set by *Roe vs Wade* (410 U.S. 113, 1973), which had recognized the right to abortion under framework of the XIV amendment, affirming the right to make free

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<sup>31</sup> A note to the judgement in G. Caporali, *Dobbs v. Jackson: la teoria originalista e i limiti all’attivismo creativo delle Corti costituzionali*, in [www.federalismi.it](http://www.federalismi.it), 34, 2022.



decisions concerning the most intimate aspects of an individual's personal life.

The opinion of Judge S. Alito – which anticipated the orientation of the majority of the judicial body – showed that although the Supreme Court has recognized that some rights (not expressly provided for by the constitutional text) were protected in the light of the due process clause (even if not expressly provided for by the constitutional text), the right to abortion is not one of them. Therefore, the previous *Roe vs Wade* and, similarly, *Planned Parenthood of Southeastern Pa. vs Casey* (505 U.S. 833, 1992) were “terribly wrong and profoundly harmful” pronouncements, with the consequence that the subject in question had to be defined by citizens' representatives. Without going into details,<sup>32</sup> it is at least necessary to highlight how the legal framework about reproductive rights is being decided State by State. Several States have enacted laws protecting abortion rights (including Mississippi, the State where the case that eventually reached the Supreme Court originated). In other States (such as California, Florida, and Massachusetts), State High Courts have interpreted their Constitutions as providing stronger protections for abortion rights or ensuring greater access than the Federal Constitution does.

In addition to the enormous clamor aroused in public opinion, there were significant implications after the *Dobbs* ruling also regarding the pharmaceutical policies adopted by the Biden Administration. In fact, President Biden proceeded to issue two EOs: EO 14076, of July 2022, Protecting Access to Reproductive Healthcare Services, and the EO 14079, of August, 2022, Securing Access to Reproductive Health Care. Through the first measure, signed by the President just two weeks after the decision of the Supreme Court, retail pharmacies were allowed to sell the abortion pill; on this point, the FDA gave its consent, and the measure was implemented starting from January 2023. The motivations rely precisely on the effects of the decision and on the fact that access to reproductive healthcare services was threatened for millions of Americans, especially for those who lived in States that were banning or severely restricting abortion care. Specifically, the executive order states: “Within 30 days of the date of this order, the Secretary of Health and Human Services shall submit a report to the President”. This report includes a series of actions aimed at protecting women's health and addressing issues related to reproductive rights.<sup>33</sup> The

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<sup>32</sup> The US Supreme Court's decision is available at [https://www.supremecourt.gov/opinions/21pdf/19-1392\\_6j37.pdf](https://www.supremecourt.gov/opinions/21pdf/19-1392_6j37.pdf). For a summary, see [https://www.cortecostituzionale.it/documenti/segnalazioni\\_corrente/Segnalazioni\\_1656319139349.pdf](https://www.cortecostituzionale.it/documenti/segnalazioni_corrente/Segnalazioni_1656319139349.pdf).

<sup>33</sup> According to *Sec. 3*, the report will have proposals aimed at “(A) to protect and expand access to abortion care, including medication abortion; and (B) to otherwise protect and expand access to the full range of reproductive healthcare services, including actions to enhance family planning services such as access to emergency contraception; (ii) identifying ways to increase outreach and education about access to reproductive healthcare services, including by launching a public awareness initiative to provide timely and accurate information about such access, which shall: (A) share information about how to obtain free or reduced cost reproductive healthcare services through Health Resources and Services Administration-Funded Health Centers, Title X clinics, and other providers; and (B) include promoting awareness of and access to the full range

second EO contained some actions to address the multiple legal uncertainties deriving from the Dobbs ruling.

Recently, the issue of reproductive drugs became a central issue in the democratic election campaign and President Biden proposed a law to provide full insurance coverage for the contraceptive pill.

### 3. Conclusion

In conclusion, the pharmaceutical policy in the Biden agenda has addressed a wide range of topics and not only – as presumable – the actions to control COVID-19. As described in the paragraphs above, there were at least three main areas of intervention, some of which continued the legacy of Obamacare. In particular, President Biden pharmaceutical policy focused on three key issues: lowering prescription drug costs for Americans, strengthening Americans' access to health coverage, and addressing the distribution of the abortion pill following the US Supreme Court Dobbs decision. Specifically, the analysis of the regulation and the EOs shows that the lowering drug costs was the main issue in the Biden agenda; after all, this specific area has to be interpreted join to the “Biden Economy”.

More broadly, it could be stated that President Biden political orientation demonstrated a trend towards the “welfareization” of healthcare in the United States. This shift began to challenge one of the fundamental pillars that differentiates the American pharmaceutical system from those in European countries: the freedom of pharmaceutical companies to set drug prices independently.

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of contraceptive services, as well as know-your-rights information for those seeking or providing reproductive healthcare services; and (iii) identifying steps to ensure that all patients—including pregnant women and those experiencing pregnancy loss, such as miscarriages and ectopic pregnancies—receive the full protections for emergency medical care afforded under the law, including by considering updates to current guidance on obligations specific to emergency conditions and stabilizing care under the Emergency Medical Treatment and Labor Act ... and providing data from the Department of Health and Human Services concerning implementation of these efforts. (b) To promote access to reproductive healthcare services, the Attorney General and the Counsel to the President shall convene a meeting of private pro bono attorneys, bar associations, and public interest organizations in order to encourage lawyers to represent and assist patients, providers, and third parties lawfully seeking these services throughout the country”.