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# THE JUDICIARY – EXECUTIVE INTERFACE IN AREAS OF HEALTH

RTH-UHC Working Paper 2

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The Centre for Health Equity, Law & Policy of the Indian Law Society, Pune, is a research, knowledge production and advocacy forum, which works on law & policy issues related to health, embedding its work in the right to health as envisaged within India's constitutional framework and her international commitments.

### Authorship and acknowledgement

*In 2022, C-HELP was commissioned by the Governance Workstream of the Lancet Citizens' Commission on Reimagining India's Health System to conduct research into the critical intersections of rights, health and law. This research is being updated, edited and published by C-HELP in a series of working papers on the Right to Health and Universal Health Coverage in India.*

This Paper is built on the shared knowledge and experience of C-HELP. It was written by Suraj Sanap and Kajal Bhardwaj with contributions from Shivangi Rai, Harshit Pande and Gargi Mishra. The paper was edited by Vivek Divan and Kajal Bhardwaj. The content emerged from extensive research mapping on health-related laws and policies in India conducted by Kajal Bhardwaj, Vivek Divan, Shefali Malhotra, Gargi Misra, Harshit Pande, Shivangi Rai, Suraj Sanap and Disha Verma.

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## BACKGROUND

In December 2020, the Lancet Citizens' Commission on Reimagining India's Health System was set up and tasked to develop a roadmap for achieving Universal Health Coverage (UHC) in India in the next 10 years. A commentary published by the co-chairs of the Commission noted that, *"underpinning the Commission's work is a normative commitment to strengthening India's public health system in all its dimensions, including promotive, preventive, and curative care."*<sup>i</sup> Some of the key questions identified for the Commission's work include, *"negotiating the intersections and complementarities between public and private health provision and the design of a regulatory structure that holds each component of the health system accountable; addressing the role of traditional systems of medicine; negotiating the federal dimensions and associated heterogeneity of health systems' capacity across India's states to articulate the distinctive roles and responsibilities of the central, state, and local governments in delivering and regulating health care; and building health system capacity for enabling and regulating the use of technology in a way that supports and strengthens health delivery while protecting citizens' rights."*<sup>i</sup>

The Commission recognises that its work requires consultative and participatory engagement. Its many workstreams represent this attempt at multisectoral collaboration, with its Governance workstream seeking to *"articulate pathways for building a robust and accountable governance framework...to achieve a vision of universal health coverage which is equitable, affordable, and accessible to all."*<sup>ii</sup> In particular, this workstream focuses on health sector regulation, accountability, and governance systems linked with federalism that impact health delivery. All the workstreams mention the key issues of accessibility, availability, affordability, equity and citizen's engagement.

Critical to the key questions identified by the Commission is a well-rounded understanding of how legal frameworks and policy impact health – positively and negatively. Indeed, inherent to the features of equity, affordability and accessibility that the different workstreams seek to address, is the issue of rights. Experience has shown that rights-based approaches to health challenges, reflected in law, policy and practice play a vital role in positive health outcomes. The World Health Organisation (WHO) has categorically stated that, *"UHC is firmly based on the 1948 WHO Constitution, which declares health a fundamental human right and commits to ensuring the highest attainable level of health for all."*<sup>iii</sup> While the co-chairs' commentary suggests that the Commission's work may, *"serve as the foundation for propelling a citizens' movement to demand the practical realisation of the aspiration of health as a fundamental right"*<sup>i</sup> it may be noted that the right to health is already well-recognised and articulated in Indian jurisprudence and law. The commentary also notes that the Commission would focus only on the *"architecture of India's Health System."*<sup>i</sup> However, the links between the right to health and UHC may require the Commission to also take into account the social determinants of health.

In this background, an examination of health-related law/ policy frameworks and developments in the context of rights becomes essential to informing the Commission's findings and recommendations on UHC. C-HELP was commissioned by the Governance workstream of the Lancet Commission to conduct research in this regard. The outcomes of that research are being updated, edited and published by C-HELP in four working papers on the Right to Health and UHC in India:

- **Working Paper 1** provides a framework of analysis to apply the right to health to UHC, articulating linkages between the two and accounting for contemporary debates and critiques of UHC.
- **Working Paper 2** presents an overview of judicial pronouncements on health, the roles of central and state governments in health and regulation of the private health sector.
- **Working Paper 3** examines the implementation of the right to health through laws and policies in India while also exploring lessons from the implementation of rights-based social sector laws.
- **Working Paper 4** explores legal-ethical issues that arise in the use of digital technologies in health.

i. Patel, V., Mazumdar-Shaw, K., Kang, G., Das, P., & Khanna, T. (2021). Reimagining India's health system: A Lancet citizens' commission. *The Lancet*, 397(10283), 1427–1430. Available at: [https://doi.org/10.1016/s0140-6736\(20\)32174-7](https://doi.org/10.1016/s0140-6736(20)32174-7).

ii. Workstreams - Reimagining India's Health System – Citizens health. Available at: <https://www.citizenshealth.in/workstreams/>

iii. World Health Organisation. (2022, December 12). Universal Health Coverage. Factsheet. Available at: [https://www.who.int/news-room/fact-sheets/detail/universal-health-coverage-\(uhc\)](https://www.who.int/news-room/fact-sheets/detail/universal-health-coverage-(uhc))

## 1. INTRODUCTION

### 1.1 Objective of the paper

The Constitution of India promises social, economic and political justice and confers powers on courts to protect this foundational principle. Accordingly, courts have adjudicated litigations concerning implementation of healthcare laws, policies and programmes, many of which implicate focus areas integral to any framework for universal health coverage (UHC) in India. Any proposal for UHC in India must keenly engage with the views of courts in monitoring and implementing commitments to health.

With an irrefutable recognition of the right to health in domestic and international law<sup>1</sup>, Indian courts have intervened in matters ranging from universal access to infectious disease programmes, availability of human resources for health, regulation of the private sector and more. These interventions provide insight on the legal obligations by State and non-State actors and the range of judicial directions to actualize them.

Through the following sections, this paper demonstrates the contours of judicial intervention in areas of health and its engagement with central and state governments on jurisdictional, financial and technical matters. In so doing, the paper indicates the ways in which governance for health has been dealt with and shaped by the courts.

This paper is divided into four sections. Section 1 presents a broad overview of the sources of legally binding commitments of the government on realization of the right to health. Section 2 deals with the powers of constitutional courts as a backdrop to the recognition of a fundamental right to health and presents a review of jurisprudence on health and health related matters. Section 3 engages with two key areas of inquiry identified in consultation with the Governance Workstream as relevant to UHC debates in India i.e., the interface of constitutional courts with the legal landscape that informs the federal arrangements of central and state governments in relation to health, and court interventions in relation to the private healthcare sector to ensure that it respects, protects and fulfils the right to health. Section 4 offers key conclusions from the review of judicial interventions in health.

### 1.2 Sources of health-related law and policy related to the right to health

The High Courts and the Supreme Court are tasked with interpretation of law and enforcement of rights as constitutional courts. Below is a brief overview of the substantive sources of law and policy that courts rely on in enforcing the fundamental right to health.

#### ***Constitution of India***

The Constitution of India is the highest law of the land. Part III of the Constitution recognizes the fundamental rights of people, mainly civil and political rights, which are enforceable by High Courts and the Supreme Court. These include the right to equality (Article 14) and freedom from discrimination (Article 15), equality of opportunity in employment (Article 16), abolition of untouchability (Article 17), free speech and assembly (Article 19) and the right life and liberty (Article 21).<sup>2</sup>

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<sup>1</sup> For a detailed discussion on the Right to Health and UHC, see C-HELP (2023), Right to Health and Universal Health Coverage in India, RTH-UHC Working Paper 1.

<sup>2</sup> Part III: Fundamental Rights, Constitution of India

It is the hitherto unenforceable Directive Principles of State Policy (DPSP) in Part IV, which codify social and economic rights, where the Constitution explicitly provides that “*the State shall regard the raising of the level of nutrition...and the improvement of public health as among its primary duties.*”<sup>3</sup>

The Seventh Schedule of the Constitution provides the legislative and administrative framework within which both central and state governments function. Although health explicitly falls within the jurisdiction of states,<sup>4</sup> various aspects impacting it fall under the Central<sup>5</sup> or Concurrent lists<sup>6</sup> of the Constitution, resulting in laws relating to health (including the social determinants of health) being legislated at both the central and state levels.

### **Statutes**

Parliament and state legislatures are tasked with the function of issuing legislation and have enacted various laws that include rights-based entitlements to healthcare goods, services and facilities –the *Human Immunodeficiency Virus and Acquired Immune Deficiency Syndrome (Prevention and Control) Act, 2017 (HIV Act)* and the *Assam Public Health Act, 2010* being two examples– as well as regulatory laws which monitor the duties of government bodies, healthcare establishments and the private sector, such as the *Clinical Establishments (Registration and Regulation) Act, 2010* and the *Pre-Conception and Pre-Natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994*.

These statutory laws create legally binding rights and obligations, and in the event of non-enforcement or violations, affected individuals and bodies can seek redressal from appropriate forums and constitutional courts.

### **Policies**

The Executive is tasked with the function of administrative governance at the central, state and district levels and has issued policies with respect to national rural and urban health programmes,<sup>7</sup> medico-legal protocols for survivors of gender-based violence<sup>8</sup> and rare diseases,<sup>9</sup> among others.

All laws in India must comply with Fundamental Rights in the Constitution. Article 13 of the Constitution defines ‘law’ as ‘including’ any ordinance, order, byelaw, rule, regulation, notification, custom or usage having the force of law. Policies issued under a statute or a provision of the Constitution would fall within this definition. Moreover, policies as a form of State action are enjoined to meet the requirements of fundamental rights. For instance, the State cannot discriminate against citizens on grounds of religion, race, caste, sex (including gender), place of birth or sexual orientation; this includes through policies. Restrictions on fundamental rights such as reasonable restrictions on the freedom of speech or assembly must be contained in law; a person (including a non-citizen) may only be deprived of life or liberty through procedure established by law. While courts are generally reticent to interfere with executive actions including policies, where these violate fundamental rights, courts do have the jurisdiction to examine policies, ensure or monitor their enforcement where not doing so violates fundamental rights, require

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<sup>3</sup> Article 47, Constitution of India.

<sup>4</sup> Public health, sanitation, hospitals and dispensaries are listed in Entry 6, List II (State List) of the Seventh Schedule to the Constitution of India.

<sup>5</sup> The Centre has the power to make laws with respect to matters not enumerated in the State or Concurrent Lists, as provided in Entry 97 of List I (Union List) of the Seventh Schedule to the Constitution of India.

<sup>6</sup> Mental healthcare (Entry 16), Adulteration of foodstuffs (Entry 18), Drugs (Entry 19), and Population control and Family planning (Entry 20-A) are listed in List III (Concurrent List) of the Seventh Schedule to the Constitution of India.

<sup>7</sup> National Rural Health Mission, Framework of Implementation (2005-2012), Ministry of Health and Family Welfare, Government of India; National Urban Health Mission, Framework of Implementation (2013), Ministry of Health and Family Welfare, Government of India

<sup>8</sup> Ministry of Health and Family Welfare (2014). Guidelines and Protocols: Medico-legal care for survivors of sexual violence.

<sup>9</sup> Ministry of Health and Family Welfare. (2021). National Policy for Rare Diseases, 2021. Available at: <https://main.mohfw.gov.in/sites/default/files/Final%20NPRD%2C%202021.pdf>

changes where they fail the requirements of Part III of the Constitution and in some cases to even require the formulation of policies to prevent rights violations. Several such cases have taken place in the context of health and are discussed in greater detail below.<sup>10</sup>

### **Judicial orders**

Courts have given meaning to the right to life under Article 21 of the Constitution by explicitly including within its ambit the right to health in a series of orders. These foundational cases establish a justiciable right, which form the bedrock of judicial interventions today in recognising, expanding and enforcing various facets of the right to health. Over time, the normative contents of the right to health under Indian law have been progressively expanded by constitutional courts to include a range of freedoms (the right to control one's body) and entitlements (the right to enjoy the highest attainable standard of health including the social determinants of health), as discussed in Section 2.

### **International law**

India's healthcare obligations also derive from international treaties and commitments that India is signatory to. In particular, the right to health is recognized in Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR).<sup>11</sup> This area of law merits a brief overview in order to reinforce the accountability of the central and state governments to respect commitments arising from international human rights law and power of Indian constitutional courts to enforce them.

The Committee on Economic, Social and Cultural Rights (CESCR), an expert body that monitors implementation of the ICESCR, has issued General Comment No. 14 (General Comment 14 or Comment)<sup>12</sup> to provide guidance to member states. The committee defines the normative content of the right to health as an inclusive right and obliges member states to focus on *availability, accessibility, acceptability* and *quality* (AAAQ) of healthcare goods, services and facilities as well as the underlying determinants of health (water, sanitation, nutrition, housing, occupational health, environment) and access to information, education and counselling. It also prescribes *general, specific* and *core* obligations by member States. These norms are discussed further in the review of reported cases in Section 2.4.

ICESCR mandates that all member states shall “*take steps, individually and through international assistance and co-operation,*”<sup>13</sup> to the maximum of available resources, with a view to “*achieving progressively the full realization of convention rights*”<sup>14</sup> by all appropriate means, including the adoption of legislative measures. The progressive realization of the right to health means that member States have

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<sup>10</sup>See for example, *Laxmi Mandal and others v Deen Dayal Harinagar Hospital & others* (2010) 172 DLT 9

<sup>11</sup> 1. *The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.*

2. *The steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for:*

(a) *The provision for the reduction of the stillbirth-rate and of infant mortality and for the healthy development of the child;*

(b) *The improvement of all aspects of environmental and industrial hygiene;*

(c) *The prevention, treatment and control of epidemic, endemic, occupational and other diseases;*

(d) *The creation of conditions which would assure to all medical service and medical attention in the event of sickness.*, Article 12, International Covenant on Economic, Social and Cultural Rights. (1966, December 16). Available at: <https://www.ohchr.org/en/instruments-mechanisms/instruments/international-covenant-economic-social-and-cultural-rights>

<sup>12</sup> Committee on Economic, Social and Cultural Rights. (2000). General Comment 14. (Twenty-second session, 2000), U.N. Doc. E/C.12/2000/4. Available at <https://www.refworld.org/pdfid/4538838d0.pdf>

<sup>13</sup> International Covenant on Economic, Social and Cultural Rights. (1966, December 16). Available at: <https://www.ohchr.org/en/instruments-mechanisms/instruments/international-covenant-economic-social-and-cultural-rights>

<sup>14</sup> Ibid.

a binding, “specific and continuing obligation to move as expeditiously and effectively as possible towards the full realization of rights.”<sup>15</sup>

Equality of access to healthcare goods, services and facilities is an integral component of the right to health. Member states are obliged “to integrate gender in all health-related decision-making processes”<sup>16</sup> to promote better health for both women and men. “In all policies and programmes aimed at guaranteeing the right to health of children and adolescents, their best interests”<sup>17</sup> must be the primary consideration. Development related activities that lead to the displacement of indigenous people “against their will from their traditional territories and environment, denying them their sources of nutrition and breaking their symbiotic relationship with their lands, has a deleterious effect on their health.”<sup>18</sup> Additionally, member states have a special obligation to prevent discrimination on internationally prohibited grounds in provision of healthcare. As such, a broader spectrum of international human rights law also articulates specific and binding obligations of member states on health, such as the Convention on Elimination of All Forms of Discrimination Against Women (CEDAW),<sup>19</sup> the Convention on the Rights of the Child<sup>20</sup> (CRC) and the United Nations Declaration on the Rights of Indigenous People.<sup>21</sup>

The United Nations Special Rapporteur (UNSR) on the Right of Everyone to the Highest Attainable Standard of Physical and Mental Health is an independent expert whose mandate includes publishing thematic reports and making recommendations to member states on the implementation of convention rights. Indian constitutional courts rely on UNSR reports to guide the interpretation and enforcement of domestic law in compliance with international law.<sup>22</sup> The UNSR on the Right to Health has observed in a series of reports that:

- i. Availability of financial resources for health in state budgets is closely linked to the principle of progressive realization of the right to health, thereby, establishing a binding, specific and continuing obligation for member states;
- ii. Inadequate expenditures or misallocation of public resources, by prioritizing expensive curative health services instead of affordable primary and preventive health services, can result in indirect discrimination against the most vulnerable in health systems and constitute a violation of convention rights;<sup>23</sup>
- iii. The right to health framework is concerned with both processes and outcomes. It is not only interested in *what* a health system delivers (access to life saving medicines and safe water), but also *how* it delivers it (transparency, participatory and non-discrimination).<sup>24</sup>

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<sup>15</sup> Ibid.

<sup>16</sup> Ibid.

<sup>17</sup> Ibid.

<sup>18</sup> Ibid.

<sup>19</sup> Convention on the Elimination of All Forms of Discrimination Against Women (1979, December, 18)

<sup>20</sup> Convention on the Rights of the Child. (1989, November, 20)

<sup>21</sup> United Nations Declaration on the Rights of Indigenous People. (2007, September, 13)

<sup>22</sup> *Patan Jamal Vali v State of Andhra Pradesh*, 2021 SCC Online SC 343

<sup>23</sup> Interim Report of the United Nations Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health. (2012). U.N. Doc. A/67/302

<sup>24</sup> Report of the United Nations Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health. (2008). UN Doc. A/HRC/7/11.



- iv. Member states must ensure that focus on addressing financial exclusion under UHC does not neglect the equally important issue of anti-discrimination on basis of prohibited grounds like gender, caste, disability or other status.<sup>25</sup>

There is a strong presumption that retrogressive measures with respect to right to health are not permissible. If taken, member States have a burden to prove they are introduced after careful consideration of alternatives and are justified in the totality of convention rights in context of full utilization of member State's available resources.

The inability of a member State in realizing the right to health due to resource constraints is differentiated from the opposition of a member State in taking appropriate measures in utilizing the maximum available resources to realize the right to health. In case of inability, a member State has a burden to justify that it has undertaken every effort to use maximum available resources at its disposal in realizing the right to health. In case of opposition, a member State's refusal to take appropriate measures will be a violation of convention rights and can be held accountable before domestic constitutional courts.

As illustration, provisions of the *Rights of Persons with Disabilities Act, 2016*<sup>26</sup>(RPD Act) and the *HIV Act*<sup>27</sup> which qualify State obligations on the basis of resource constraints must not to be interpreted as *carte blanche* exemptions from performing its constitutional duty. If the government faces resource constraints in implementation of its obligations under the law, it has a burden to justify that it has undertaken every effort to use maximum available resources at its disposal.

While General Comment No. 24<sup>28</sup> does not view privatization as *per se* prohibited by the ICESCR, on basis of evidence-informed reports of the failure of privatization in ensuring better quality and access to essential public services like water, sanitation, healthcare and education, the CESCR recommends that private providers should be subject to strict regulations, which impose public service obligations. It further adds that privatization should not result in the enjoyment of convention rights being conditional on the ability to pay.

Indian constitutional courts have routinely held that as India has ratified ICESCR, the international human rights norms on health therein are legally binding and mandate the Government of India to progressively realize the right to health.<sup>29</sup> Additionally, the *Protection of Human Rights Act, 1993* (PHRA) expressly recognizes ICESCR as a component of India's human rights law regime.<sup>30</sup>

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<sup>25</sup> Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health. (2016). UN Doc. A/71/304

<sup>26</sup> Section 24: Central and State governments shall *within the limits of its economic capacity and development* formulate social security schemes to safeguard and promote the right of persons with disabilities to an adequate standard of living, including provision of aids and appliances, medicines and diagnostic services and corrective surgery free of cost to persons with disabilities with such income ceilings as may be notified...

<sup>27</sup> Section 14: Central and State governments shall take all measures to prevent and control HIV/AIDS, which shall include, *as far as possible*, diagnostics, ART medicines and treatment for opportunistic infections...

<sup>28</sup> Committee on Economic, Social and Cultural Rights. (2017) General Comment No. 24 on State Obligations Under the International Covenant on Economic, Social and Cultural Rights in the Context of Business Activities. U.N. Doc. E/C.12/GC/24.

<sup>29</sup> Id at 10, *Laxmi Mandal*

<sup>30</sup> Section 2(d) of PHRA defines "human rights" to mean "*the rights relating to life, liberty, equality and dignity of the individual guaranteed by the Constitution or embodied in the International Covenants and enforceable by Courts in India*". Section 2(f) of PHRA defines "International Covenants" to mean "*the International Covenant on Civil and Political Rights and the International Covenant on Economic, Social and Cultural Rights adopted by the General Assembly of the United Nations on the 16<sup>th</sup> December, 1966.*"

As India follows the dualist system, treaties and international agreements entered into by the government are not directly enforceable unless Parliament passes a law to bring them into effect.<sup>31</sup> However, in absence of domestic laws to the contrary, courts have the power to rely on treaties and international agreements to interpret domestic law and pass appropriate relief.<sup>32</sup>

India is also a signatory to resolutions/declarations at the UN relating to international commitments on health, including HIV,<sup>33</sup> sustainable development goals (SDGs)<sup>34</sup> and UHC.<sup>35</sup> Although not legally binding *per se*, they are founded in universal human rights principles and include a commitment for implementation as per domestic and international legal commitments of member States. These international processes impact health in India in multiple ways and can be basis for undertaking legislative efforts,<sup>36</sup> changes in policies<sup>37</sup> or in the reasoning of court decisions.<sup>38</sup>

## 2. JUDICIAL REVIEW OF EXECUTIVE AND LEGISLATIVE ROLES

### 2.1 Writ Jurisdiction of Constitutional Courts

Crucial to understanding how the right to health has been shaped by the courts, an overview of the scope of judicial authority and its interplay with other governmental organs is necessary.

The Supreme Court of India is one of the most powerful apex courts in the world as it has extensive powers under the Constitution.<sup>39</sup> Its powers include interpretation of law, judicial review of laws and State action, enforcement of fundamental rights, plenary powers to do 'complete justice' and commanding authority over all civil and judicial authorities in India to act in aid of its orders.<sup>40</sup> Access to judicial remedy before the Supreme Court under Article 32(1) is a fundamental right in itself.

High Courts at the state level are conferred with similar powers for state-level jurisdiction under the Constitution.<sup>41</sup> Article 226 of the Constitution empowers High Courts to issue directions, orders or writs to 'any person' or 'authority,' including 'any government authority,' for the enforcement of fundamental rights or for 'any other purpose'. This latter phrase has been interpreted to mean in relation to functions or duties performed by public authorities or the appropriate government.<sup>42</sup> Apart from enforcement of fundamental rights, High Courts can exercise jurisdiction for enforcement of any legal right conferred by

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<sup>31</sup> Article 253, Constitution of India

<sup>32</sup> *National Legal Services Authority v Union of India* (2014) 5 SCC 438

<sup>33</sup> Declaration of Commitment on HIV/AIDS, 2001

<sup>34</sup> United Nations General Assembly. (2015). *Transforming our world: the 2030 Agenda for Sustainable Development*.

A/RES/70/1. Available at:

[https://www.un.org/en/development/desa/population/migration/generalassembly/docs/globalcompact/A\\_RES\\_70\\_1\\_E.pdf](https://www.un.org/en/development/desa/population/migration/generalassembly/docs/globalcompact/A_RES_70_1_E.pdf)

<sup>35</sup> United Nations General Assembly. (2019). *Political Declaration of the High-level Meeting on Universal Health Coverage*.

Available at: <https://www.un.org/pga/73/wp-content/uploads/sites/53/2019/07/FINAL-draft-UHC-Political-Declaration.pdf>

<sup>36</sup> *Human Immunodeficiency Virus and Acquired Immune Deficiency Syndrome (Prevention and Control) Act, 2017*

<sup>37</sup> Id at 10, *Laxmi Mandal*

<sup>38</sup> *Justice KS Puttaswamy and Another v Union of India and others* (2017) 10 SCC 1

<sup>39</sup> Baxi, U, 'Taking Suffering Seriously: Social Action Litigation in the Supreme Court in India' (1985) 4 *Third World Legal Studies* 107; Sathe, S.P., 'Judicial Activism: The Indian Experience' (2001) 6 *Washington University Journal of Law* 29; Cunningham, C.D., 'The World's Most Powerful Court: Finding the Roots of India's Public Interest Litigation Revolution in the Hussainara Khatoon Prisoners Case' in SP Sathe (ed) *Liberty, Equality and Justice: Struggles for a New Social Order* (Eastern Book Company 2003).

<sup>40</sup> Articles 124-147, Chapter IV-Union Judiciary, Part V-The Union, Constitution of India

<sup>41</sup> Articles 214-232, Chapter V-High Courts in the States, Part VI-The States, Constitution of India

<sup>42</sup> *G. Bassi Reddy v International Crops Research Institute* (2003) 4 SCC 225

a statute.<sup>43</sup> They can exercise writ jurisdiction even in matters where an alternative statutory remedy is available, if the matter relates to fundamental rights.<sup>44</sup>

Articles 32 and 226 of the Constitution respectively authorize the Supreme Court and High Courts to issue appropriate directions, orders or writs (in the nature of *habeas corpus*, *mandamus*, prohibition, *quo warranto*, and *certiorari*)<sup>45</sup> in exercise of its writ jurisdiction. This power of judicial review of laws or State action is integral to the 'basic structure of the Constitution' which can never be amended and ousted by Parliament.<sup>46</sup>

All executive/administrative and legislative decisions of the government are amenable to judicial review and constitutional courts can quash the act under challenge which is contrary to statutory or administrative law or violates fundamental rights under the Constitution.<sup>47</sup>

The conventional rules of procedure of the adversarial system of litigation permit only a person whose rights are directly impacted to seek legal remedies. However, writ jurisdiction has evolved to allow any member of the public to seek redressal in good faith, where the aggrieved party may be impeded from directly approaching courts due to socio-economic reasons, as the violation of constitutionally protected rights impact the public as a community.<sup>48</sup> Additionally, in order to facilitate access to justice, public interest litigation (PIL) under writ jurisdiction is marked by relaxation in the manner of filing petitions, appointment of fact-finding commissions, submission of expert reports before court and the designation of senior advocates as *amicus curiae* to assist the courts.<sup>49</sup>

As a derivative of PILs, constitutional courts can exercise writ jurisdiction to initiate *suo moto* matters, i.e., they take up cases on their own notice, without requiring a petition to be filed for a claim to be adjudicated. Courts typically initiate such proceedings on the basis of news reports or letters addressed to it,<sup>50</sup> and have intervened to pass directions in matters ranging from prevention of torture in prisons,<sup>51</sup> implementation of infectious disease programmes to treat swine flu<sup>52</sup> and the labour migration and treatment access crises during COVID-19.<sup>53</sup>

Constitutional courts can determine cases on a 'continuing mandamus' basis, i.e., cases remain open to review of implementation of the court's directions and fresh orders can be issued without having to institute a new case.<sup>54</sup> Courts have monitored the progress of provision of social security benefits by state governments in events of climate-change induced disasters,<sup>55</sup> availability of healthcare services for

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<sup>43</sup> *Dwarka Prasad Agarwal v BD Agarwal* (2003) 6 SCC 230

<sup>44</sup> *United Bank of India v Satyavati* (2010) 8 SCC 110

<sup>45</sup> *Habeas corpus* is a writ requiring a person under arrest or illegal detention (by a public authority or a private entity) to be produced before a court, in order to protect personal liberty, unless lawful grounds are shown for the detention. *Mandamus* is a writ issued as a command to a lower court or a public authority to perform its lawful duty. Prohibition is a writ issued to prevent a lower court or a public authority from exceeding its jurisdiction or acting contrary to law. *Quo warranto* is a writ issued seeking justification of the legal validity of any act by a public authority. *Certiorari* is a writ issued for quashing an order of a lower court and transferring jurisdiction unto itself.

<sup>46</sup> *L. Chandra Kumar v Union of India and others* (1997) 3 SCC 261

<sup>47</sup> *Common Cause v Union of India* (1999) 6 SCC 667

<sup>48</sup> Public Interest Litigation: Potential and Problems, Desai, A.H. and Muralidhar, S., *Supreme but not Infallible – Essays in Honour of the Supreme Court of India*, Oxford University Press, 2000, page 161

<sup>49</sup> *Ibid*, page 162

<sup>50</sup> Galanter, M., and Ram, V., 'Suo Moto Intervention and the Indian Judiciary', Rosenberg et al (eds), *A Qualified Hope*, Cambridge University Press, 2019

<sup>51</sup> *Sunil Batra v. Delhi Administration* (1980) 3 SCC 488

<sup>52</sup> *Suo Moto v. State of Rajasthan*, Civil WP (PIL) No. 1365/2015

<sup>53</sup> *In Re: Problems and Miseries of Migrant Labourers*, *Suo Moto* WP (C) No. 6/2020

<sup>54</sup> *Vineet Narain v Union of India* (1998) 1 SCC 226

<sup>55</sup> *Swaraj Abhiyan v Union of India* (2016) 7 SCC 498

children in juvenile homes,<sup>56</sup> access to food security for prevention of malnutrition-related maternal and child deaths<sup>57</sup> and access to anti-retroviral treatment for HIV.<sup>58</sup>

The doctrine of separation of powers proposes that any arm of the State (judiciary, legislature and executive) must not occupy the other's powers as provided in the Constitution. However, in areas where a legislative or executive/administrative vacuum exists, constitutional courts can exercise writ jurisdiction to issue directions that occupy the field of law, until a legislation<sup>59</sup> or policy/guideline<sup>60</sup> is formulated. It bears well to note that a law or policy/guideline drafted after such judicial intervention must be consistent with the declared law rather than overrule it, in order to withstand constitutional validity.<sup>61</sup> In aid of this exercise, courts have interpreted law to provide substantive relief and procedural remedies in matters relating to sexual harassment at the workplace,<sup>62</sup> protection of socio-economic rights of the transgender community<sup>63</sup> and guaranteeing occupational health and safety of sewage workers.<sup>64</sup>

## 2.2 The Constitution as a Living Bill of Rights

A summary of the evolution of the Constitution as it has been interpreted towards a more progressive rights-bestowing document is useful in order to contextualise the development of a right to health under the right to life and liberty. This evolution has been aptly described by the Supreme Court in *KS Puttaswamy (I) v Union of India*<sup>65</sup> as the move from "originalist" interpretations to a "living constitutionalist" approach.

Article 21 of the Constitution reads: "*Protection of life and personal liberty – No person shall be deprived of his life or personal liberty except according to procedure established by law*".

After the Constitution came into force, the governing framework of constitutional law was based on an *originalist* doctrine for nearly two and a half decades, which essentially postulated:

- i. The object and purpose of impugned State action was central to a review of its validity for determination of violation of fundamental rights;
- ii. Article 21 related to direct restrictions on 'personal liberty' of individuals, i.e., it was limited in application to review cases of bodily restraint like illegal or preventive detention;
- iii. Fundamental rights in Part III of the Constitution are mutually exclusive and do not impact each other's content. As such, guarantees of equality (Article 14), anti-discrimination (Article 15) and reasonability of restrictions on rights (Article 19) would be inapplicable in cases of preventive detention (Article 22);<sup>66</sup>
- iv. Article 21 could be suspended in the event the government invokes emergency powers under the Constitution.<sup>67</sup>

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<sup>56</sup> *Sampurna Behura v Union of India* (2018) 4 SCC 433

<sup>57</sup> *People's Union for Civil Liberties (PUCI) v Union of India & Others*, WP (Civil) No. 196/2001

<sup>58</sup> *Sankalp Rehabilitation Trust v Union of India*, WP (C) No. 512/1999

<sup>59</sup> Article 141-142 of the Constitution of India

<sup>60</sup> *Mohd. Ahmed (minor) v Union of India* (2014) 6 HCC (Del) 118

<sup>61</sup> *Madras Bar Association v Union of India* 2021 SCC Online SC 463, para. 44; *Master Arnesh Shaw v Union of India*, WP (C) No. 5315/2020

<sup>62</sup> *Vishaka v State of Rajasthan* (1997) 6 SCC 241

<sup>63</sup> *National Legal Services Authority (NALSA) v Union of India* (2014) 5 SCC 438

<sup>64</sup> *Delhi Jal Board v National Campaign for Dignity and Rights of Sewerage and Allied Workers* (2011) 8 SCC 568 (2017) 10 SCC 1

<sup>66</sup> *AK Gopalan v State of Madras* AIR 1950 SC 27

<sup>67</sup> *ADM, Jabalpur v Shivkant Shukla* (1976) 2 SCC 248

In the years leading up to the Emergency (1975-1977) and beyond, this framework of constitutional law transformed when the court declared what is today termed as the *living constitutionalism* doctrine in a series of cases:

- i. The standard of review of State action evolved by mandating that validity must be assessed on basis of the *impact* of the impugned State action on fundamental rights, thereby, overruling the *originalist* doctrine;<sup>68</sup>
- ii. Fundamental rights in Part III of the Constitution form an interdependent collective of guarantees against State interference;<sup>69</sup>
- iii. 'Personal liberty' in Article 21 is not limited to bodily restraint, rather, covers a range of fundamental rights, including the right to travel to a foreign country under Article 19;<sup>70</sup>
- iv. An exercise of interpreting fundamental rights in Part III with DPSPs in Part IV of the Constitution made socio-economic rights a justiciable reality.<sup>71</sup>
- v. Articles 14, 19 and 21 read jointly provide a guarantee that the 'procedure established by law' which imposes restraints on fundamental rights must be fair, just and reasonable;<sup>72</sup>
- vi. Article 21 cannot be suspended in the event the government invokes emergency powers under the Constitution as it is an inalienable right.<sup>73</sup>

This is the settled jurisprudential foundation of constitutional law as applicable today, marking a transition from parliamentary supremacy to constitutional supremacy. A defining feature of the *living constitutionalism* doctrine is the articulation that fundamental rights are not bestowed by the State, rather, they pre-date the State, inhere in all individuals by virtue of being human and are therefore inalienable rights. This heralded a complete reversal of the *originalist* doctrine as Article 21, though textually reading as authority of the State to interfere with fundamental rights, is interpreted as a positive right which merits paramount status in a constitutional democracy governed by the rule of law.<sup>74</sup>

The doctrine of *living constitutionalism* postulates that the Constitution must not be frozen in its original framing. Instead, it must be construed having regard to the march of time, development of law and respond to aspirations of the people.<sup>75</sup> Particularly for the purposes of this paper, the interplay between Part III and Part IV of the Constitution making socio-economic rights justiciable<sup>76</sup> means that Article 21 is now interpreted to mean that 'life' does not mean merely physical existence, it includes the right to live with human dignity,<sup>77</sup> and this view has grown progressively to include guarantees of second-generation freedoms like the right to privacy<sup>78</sup> and entitlements like the right to a pollution-free environment.<sup>79</sup>

### 2.3 Judicial review of health-related laws, policies and programmes

With this overview of constitutional courts' powers, it is pertinent to discuss these court interventions to review laws, policies and programmes from the perspective of Article 21-related rights, including the right to health.

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<sup>68</sup> *RC Cooper v Union of India* (1970) 1 SCC 248

<sup>69</sup> *RC Cooper v Union of India* (1970) 1 SCC 248

<sup>70</sup> *Satwant Singh Sawhney v D. Ramarathnam* AIR 1967 SC 1836

<sup>71</sup> *State of Kerala v NM Thomas* (1976) 2 SCC 310

<sup>72</sup> *Maneka Gandhi v Union of India* (1978) 1 SCC 248

<sup>73</sup> Constitution (Forty Fourth Amendment) Act, 1978; *KS Puttaswamy (I) v Union of India* (2017) 10 SCC 1, paras. 136-141

<sup>74</sup> *KS Puttaswamy (I) v Union of India* (2017) 10 SCC 1 paras. 120-125

<sup>75</sup> *I.R. Coelho v State of Tamil Nadu* (2007) 2 SCC 1, paras. 42-43

<sup>76</sup> *State of Kerala v NM Thomas* (1976) 2 SCC 310

<sup>77</sup> *Francis Coralie Mullin v Administrator, Union Territory of Delhi* (1981) 1 SCC 608, para. 8

<sup>78</sup> *Id* at 74, *Puttaswamy (I)*

<sup>79</sup> *MC Mehta v Union of India* (1987) 4 SCC 463

The power of judicial review of legislative action/statutory law, rules, etc., includes the power to read down or strike down provisions which are (i) violative of fundamental rights, (ii) manifestly arbitrary or (iii) beyond legislative competence.<sup>80</sup> Any fundamental right is not unqualified and can be lawfully restricted based on a four-fold test: (i) State action must be sanctioned by statutory law, (ii) State action must be necessary in a democratic society for a legitimate aim, (iii) extent of interference must be proportionate to the achievement of objects and (iv) provision of procedural safeguards against abuse of power.<sup>81</sup>

The power of judicial review is not restricted to test only whether the procedural content of law is fair, just and reasonable. Courts can enquire into substantive content of law to test whether they are an affirmation or denial of fundamental rights.<sup>82</sup>

Authorised as such, constitutional courts have read-down penal laws that criminalize consensual sex in private between lesbian, gay, bisexual and transgender (LGBT) adults<sup>83</sup> as well as laws that subject *hijra* communities to discriminatory and heightened police surveillance<sup>84</sup> and declared that persons with mental illness, who are convicted of offences meriting the death penalty not be executed.<sup>85</sup>

Similarly, constitutional courts have conducted reviews of health-related government programmes to monitor appropriate implementation or even require changes such as ensuring maternal health programmes are critically linked to food security entitlements,<sup>86</sup> evidence-based revision of national tuberculosis (TB) treatment protocols<sup>87</sup> and scaling-up of the HIV programme.<sup>88</sup>

However, the conventional judicial approach to policy matters involving technical questions of law and facts relating to science, technology, health, economics and others is to not intervene in such policy decisions of the executive, and to defer to the opinion of experts.<sup>89</sup> While courts will seldom undertake a review on the merits of a policy *per se*, judicial reviews still take place where a policy is manifestly arbitrary or violates any law or fundamental rights.<sup>90</sup>

Courts have intervened on this basis to monitor the framing of policy on providing treatment for rare diseases<sup>91</sup> and persuading the government to amend the liberalized COVID-19 vaccine policy to remove procurement/distribution related barriers on access to vaccination.<sup>92</sup>

The Supreme Court's articulation of the grounds for intervention in the COVID-19 vaccine case merits further attention. During the humanitarian crisis of the second wave, the central government replaced the Universal Immunization Programme (UIP), which had hitherto centrally procured essential vaccines and distributed them to states and union territories (UT) since 1978, with the Liberalized Pricing and Accelerated National COVID-19 Vaccination Strategy starting May 2021. This new policy reserved 50 percent of vaccines to be procured directly by states/UTs and private healthcare establishments from vaccine manufacturers. The Supreme Court intervened *suo moto*, affirming its constitutional duty to

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<sup>80</sup> *KS Puttaswamy (II) v Union of India* (2019) 1 SCC 1

<sup>81</sup> *Id* at 74, *KS Puttaswamy (I)*, para. 638

<sup>82</sup> *Ibid*

<sup>83</sup> *Navtej Singh Johar v Union of India* (2018) 10 SCC 1

<sup>84</sup> *Karnataka Sexual Minorities Forum v State of Karnataka* 2017 SCC Online Kar 558

<sup>85</sup> *Shatrughan Chauhan and Ors. v Union of India* (2014) 3 SCC 1

<sup>86</sup> *Id* at 10, *Laxmi Mandal*

<sup>87</sup> *Dr. Raman Kakkar v Union of India*, WP(C) No. 604/2016

<sup>88</sup> *Sankalp Rehabilitation Trust v Union of India*, WP (C) No. 512/1999

<sup>89</sup> *Academy of Nutrition Improvement v Union of India* (2011) 8 SCC 274, paras. 34-35

<sup>90</sup> *Directorate of Film Festivals v Gaurav Ashwin Jain* (2007) 4 SCC 737, para. 16

<sup>91</sup> *Master Arnesh Shaw v Union of India*, WP (C) No. 5315/2020

<sup>92</sup> *In re: Distribution of essential supplies and services during pandemic*, *Suo Moto* (Civil) WP No. 3/2021

protect fundamental rights, and sought justification for the central government's decision, as it believed the revised policy would adversely impact people's access to life-saving vaccination.<sup>93</sup>

The court noted that the policy of the central government of conducting free vaccination itself for the 45 years+ demographic under the first two phases, and replacing it with paid vaccination by states/UTs and private hospitals for the 18-44 years demographic would impede access to vaccines for the latter group, due to expensive prices. It recommended that the rational method of proceeding in a manner consistent with the right to equality under Article 14 and the right to health under Article 21 would be for the Central Government to procure all vaccines by negotiating the price with manufacturers, so that life-saving vaccines are universally accessible for everyone across all states.

Although the court did not pass a conclusive determination on the constitutionality of the revised policy, it expressed a *prima facie* view that the revised policy was potentially violative of the right to health under Article 21, and asked the central government to consider amending the policy to ensure that it withstood such constitutional scrutiny.<sup>94</sup>

The court justified its intervention as follows:

*"It is trite to state that separation of powers is a part of the basic structure of the Constitution. Policy-making continues to be in the sole domain of the executive. The judiciary does not possess the authority or competence to assume the role of the executive, which is democratically accountable for its actions and has access to the resources which are instrumental to policy formulation. However, this separation of powers does not result in courts lacking jurisdiction in conducting a judicial review of these policies. Our Constitution does not envisage courts to be silent spectators when constitutional rights of citizens are infringed by executive policies. Judicial review and soliciting constitutional justification for policies formulated by the executive is an essential function, which the courts are entrusted to perform.*

...

*In grappling with the second wave of the pandemic, this Court does not intend to second-guess the wisdom of the executive when it chooses between two competing and efficacious policy measures. However, it continues to exercise jurisdiction to determine if the chosen policy measure conforms to the standards of reasonableness, militates against manifest arbitrariness and protects the right to life of all persons."<sup>95</sup>*

It bears noting that the court's effective intervention resulted in the central government's revision of the policy to procure vaccines for distribution to state governments.<sup>96</sup> In the context of health, the court's view of its role as reviewer here is significant, given the large amount of policy that governs health delivery in India.

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<sup>93</sup> Ibid, order dated 27.04.2021, paras. 1,4

<sup>94</sup> Id at 92, *In re: Distribution of essential supplies and services during pandemic* orders dated 30.04.2021 (para. 43) and 31.05.2021 (paras. 26, 33, 43)

<sup>95</sup> Id at 92, *In re: Distribution of essential supplies and services during pandemic* order dated 31.05.2021, paras. 15, 19

<sup>96</sup> Ministry of Health and Family Welfare (2021, June 21). Revised Guidelines for Implementation of National COVID Vaccination Programme. Available at: <https://www.mohfw.gov.in/pdf/RevisedVaccinationGuidelines.pdf>

## 2.4 A Constitutional Right to Health: Highlights from key cases

In service to the doctrine of *living constitutionalism*, constitutional courts have recognized a fundamental right to health from a joint reading of Article 21 of Part III with Article 38,<sup>97</sup> Article 39(e)<sup>98</sup> and Article 47<sup>99</sup> of Part IV of the Constitution in a series of foundational cases.<sup>100</sup>

This section highlights key health-related cases that have established the right to health and led to the evolution of key parameters and components of the right to health in India. A particular focus of this section is on the myriad substantive orders, directions and judgments passed by constitutional courts that translate this right into reality. A vast majority of cases discussed below are litigated under Article 226 and Article 32, which means courts are explicitly or implicitly dealing with concerns of right to health or health-related rights under Article 21.

The cases are categorized on basis of key General Comment 14 norms (as discussed in Section 1.2) to illustrate how constitutional courts have recognised and enforced international human rights principles, explicitly or implicitly i.e. (a) the AAAQ framework, (b) the obligations to respect, protect and fulfil the right to health and (c) the social determinants of health.

### 2.4.1 Availability, Accessibility, Acceptability, Quality (AAAQ)

- i. **'Availability'** requires that functioning public health and healthcare facilities, goods and services, as well as programmes are available in sufficient quantity including the social determinants of health (safe drinking water, sanitation). The summaries of rulings below illustrate the active role of constitutional courts in ensuring a functioning public healthcare system in areas of availability of a range of needs that implicate healthcare institutions, health technologies like essential drugs, and services, health financing and human resources for health.

#### **Emergency medical services:**

- Courts have held that Article 21 casts an obligation on the government to preserve human life, particularly in emergency situations.
- Thus, doctors, whether in public or private hospitals, have been held to be obligated to provide emergency medical services.<sup>101</sup>

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<sup>97</sup> Article 38. State to secure a social order for the promotion of welfare of the people:

- (1) The State shall strive to promote the welfare of the people by securing and protecting as effectively as it may a social order in which justice, social, economic and political, shall inform all the institutions of national life.
- (2) The State shall, in particular, strive to minimize the inequalities in income, and endeavour to eliminate inequalities in status, facilities and opportunities, not only amongst individuals but also amongst groups of people residing in different areas or engaged in different vocations.

<sup>98</sup> Article 39. Certain principles of policy to be followed by the State: (e) The State shall, in particular, direct its policy towards securing that the health and strength of workers, men and women, and the tender age of children are not abused and that citizens are not forced by economic necessity to enter avocations unsuited to their age or strength

<sup>99</sup> Article 47. Duty of the State to raise the level of nutrition and the standard of living and to improve public health: The State shall regard the raising of the level of nutrition and the standard of living of its people and the improvement of public health as among its primary duties and, in particular, the State shall endeavour to bring about prohibition of the consumption, except for medicinal purposes of intoxicating drinks and of drugs which are injurious to health.

<sup>100</sup> *Parmanand Katara v Union of India* (1989) 4 SCC 286; *Paschim Banga Khet Mazdoor Samity v State of West Bengal* (1996) 4 SCC 37; *State of Punjab v Mohinder Singh Chawla and others* (1997) 2 SCC 83; *State of Punjab v Ram Lubhaya Bagga* (1998) 4 SCC 117; *Bandhua Mukti Morcha v Union of India* (1984) 2 S.C.R. 67; *Consumer Education and Research Centre v Union of India* (1995) 3 SCC 42; *United India Insurance Co. Ltd. v Manubhai Dharmasinhbhai Gajera* (2008) 10 SCC 404

<sup>101</sup> *Parmanand Katara v Union of India* (1989) 4 SCC 286



- It has been held that at a minimum, essential level, the government must discharge its obligation towards the right to health by running hospitals and health centres; primary healthcare centres (PHCs) must be adequately equipped where patients can be stabilized; district level hospitals must be upgraded for treatment of serious cases; specialist treatment facilities must be increased; a centralized system to monitor availability of hospital beds should be established; and availability of ambulances must be ensured.<sup>102</sup>

***Emergency Care for pregnant women:***

- While early cases focussed on situations of emergency care in terms of accidents, the issue of women surviving their pregnancies and the provision of emergency care in such situations has come up repeatedly before courts. High Courts have closely examined key health programmes in relation to maternal mortality and morbidity.
- The government was found to be mandated under Article 21 and Article 15 to implement National Rural Health Mission (NRHM) programmes with respect to antenatal care, delivery care and postnatal care across PHCs, community healthcare centres (CHC), district level hospitals and state medical colleges. A further obligation to constitute special committees with citizen participation to monitor status of public healthcare goods, services and facilities, fill existing vacancies of paramedical staff and medical officers, and to ensure supply to essential medicines was articulated.<sup>103</sup>
- A challenge to a Ministry of Health and Family Welfare (MOHFW) lifesaving anaesthetic skills (LSAS) training programme was dismissed on the basis that the programme was intended to respond to the high maternal mortality rates by making available emergency obstetric care at first referral units and CHCs.<sup>104</sup>

***Essential and specialist healthcare workers for backward areas:***

- Recognising the paucity of human resources for health in many parts of the country, constitutional courts have issued a variety of orders to address this concern, rooted in the commitments to social and economic justice.
- Reservation in post-graduate medical degree/diploma courses for healthcare workers from rural and tribal communities was held to be an effective policy measure for making available trained medical staff and fulfilment of access to healthcare goods, services for rural and tribal communities.<sup>105</sup>
- Compulsory public service bonds for healthcare workers/medical professionals training for superspecialist courses have been held to be constitutionally valid policy measures which impose reasonable restrictions on freedom to practice profession under Article 19(1)(g) and advance the goal of full realization of the right to health under Article 21. It has also been held that India is obligated under the ICESCR to take special measures to ensure superspecialist healthcare goods, services and facilities are available for everyone in the public healthcare system, including rural and tribal communities.<sup>106</sup>
- Government's obligation of protecting the right to health under Article 21 was found to assume more importance in the backdrop of disproportionately inadequate healthcare facilities and trained doctors in rural and hilly areas.

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<sup>102</sup> *Paschim Banga Khet Mazdoor Samity v State of West Bengal* (1996) 4 SCC 37

<sup>103</sup> *Snehalata Singh v State of Uttar Pradesh*, PIL No. 14588 of 2009, order dt. 09.03.2018

<sup>104</sup> *Urvashi Popli v Union of India* (2009) 163 DLT 124 (DB)

<sup>105</sup> *Ankit Abhishek v Dr. Ravi Ranjan Kumar* 2020 SCC Online Pat 669; *Dr. Rajendra Sadanand Burma & Ors. v State of Maharashtra*, PIL No. 133 of 2007, order dated 17.07.2015

<sup>106</sup> *Association of Medical Superspecialty Aspirants and Residents v Union of India* (2019) 8 SCC 607; *Tamil Nadu Medical Officers Association v Union of India* (2021) 6 SCC 568

### **Recruitment and working conditions for healthcare workers**

- Improving public health was held to include employment of regularized and trained healthcare workers to aid in access to goods, services and facilities. Hiring contractual staff for essential medical positions like nursing or technical staff on a governmental plea of lack of finances was found to be impermissible.<sup>107</sup>
- Anganwadi Workers (AWW) are responsible for the implementation of the Integrated Child Development Services (ICDS) programme for prevention of maternal and child malnutrition. On appraisal of their functions, which include delivery of vital services, organizing local women's self-help groups and ensuring effective convergence of government's inter-sectoral schemes, it was held that AWWs were clearly not part-time voluntary workers meriting an 'honorarium'. Rather, they were found to be employees of the State as they perform statutory functions under the *National Food Security Act, 2013* (NFSA) to advance its obligations under Article 47, and therefore serve as full-time employees who deserve payment of wages and appropriate benefits related to employment under the *Payment of Gratuity Act, 1972*.<sup>108</sup>

### **Access to essential palliative care drugs**

- In a PIL filed seeking directions to the central government to modify rules governing availability of morphine and other opioids required for pain control and management, resulted in a nearly decade-long case and a 'continuing mandamus' to ensure access to essential palliative drugs.
- The court directed the government to constitute a committee to examine the stated legal policy concerns, as it had received several representations on access to morphine and other opioids for palliative care, and drew attention to the urgent need for a uniform licensing regime under the *Narcotic Drugs and Psychotropic Substances Act, 1985* (NDPS Act).
- As directed by the court, the government held consultations with stakeholders, including the palliative care community, and passed the *NDPS (Amendment) Act, 2014* which enabled it to notify certain narcotic drugs used for medical purposes, including for palliative care and drug dependence treatment, as 'essential narcotic drugs.'
- The central government filed an affidavit stating that pursuant to the said amendments to the law, it had issued a series of notifications in exercise of powers conferred under the Act, to simplify the regime of manufacturing, possession, supply, transport, consumption, etc. of relevant essential narcotic drugs.<sup>109</sup>

### **Tax on healthcare goods and access to essential drugs (oxygen)**

- A senior citizen petitioned the court, seeking directions to the Ministry of Finance to exempt 12 percent integrated goods and services tax (IGST) on import of oxygen concentrators for personal use during COVID-19, on grounds of Articles 14 and 21.
- The ministry had also issued a notification whereby it fully exempted any IGST on oxygen concentrators if imported by State agencies, thereby, discriminating between private individuals and State agencies who imported oxygen concentrators.
- The court directed the ministry to withdraw the impugned notification, as this levy of IGST adversely affected the ability of senior citizens and other vulnerable individuals to seek life-saving goods and directly impacted the right to health under Article 21.<sup>110</sup>

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<sup>107</sup> *Gade Basaveswara Rao & Ors. v Govt. of Andhra Pradesh* (2017) 6 ALD 447

<sup>108</sup> *Maniben Bhariya v DDPO* 2022 SCC Online SC 507

<sup>109</sup> *Indian Association of Palliative Care Ors. V Union of India* 2016 SCC Online SC 587

<sup>110</sup> *Gurcharan Singh v Ministry of Finance*, WP© No. 5149/2021

- ii. **Accessibility** requires that healthcare goods, services and facilities must be accessible to everyone and without discrimination to the most vulnerable or marginalized populations. The accessibility component includes affordability of goods, services and facilities. While the cases highlighted below focus on the aspect of discrimination, the sub-section that follows on the 'obligation to fulfil' highlights several cases related to affordability.

#### ***Discrimination based on sex and gender***

- In relation to health and healthcare, courts have found both direct and indirect discrimination based on sex and gender to violate Constitutional rights.
- Denial of seniority in promotion owing to a woman police officer's inability to appear for a promotional course due to pregnancy was held to amount to indirect discrimination on the basis of sex, which violated Articles 14, 15 and 16 (equality of opportunity in public employment) and Article 21, as service regulations failed to accommodate the opportunity for pregnant female officers to comply with job requirements. The court also held that it could invoke the doctrine of indirect discrimination even if a party had not explicitly relied on it, if material on record warranted such powers.<sup>111</sup>
- Examining policies that provide access to healthcare, courts have found that even facially neutral policies may indirectly discriminate based on sex. For instance, denial of healthcare goods, services and facilities violates the right to health under Article 21 as well as the guarantee of non-discrimination as per Article 15 for marginalized communities, as facially neutral actions by the government may have an adverse and disproportionate impact on them.<sup>112</sup>
- Not only have courts struck down discriminatory policies or laws, they have also directed the provision of healthcare services without discrimination. For instance, in the case of healthcare for transgender people, the central and state governments must take appropriate measures to facilitate transgender persons' access to HIV related healthcare services, mental healthcare services, public healthcare facilities and sanitation services among others on basis of Articles 15 and 21.<sup>113</sup>

#### ***Discrimination in accessing to health insurance***

- Courts have intervened on another crucial aspect of accessibility – the ability of persons to obtain health insurance ruling against exclusions based on various conditions
- *Genetic conditions*: The right to access health insurance was held to be an inalienable part of the right to health; without it access to affordable healthcare is challenging. Exclusions on the basis of genetic heritage were held to be discriminatory under Article 14 and violate the right to health under Article 21. However, it was also held that health insurance contracts can be based on empirical data to determine the insurance provider's policy vis-à-vis any specific genetic condition(s) and payment of differential premium.<sup>114</sup>
- *Mental health*: Health insurance providers (private and public) have been directed to amend policies to remove exclusions on basis of mental health conditions as the *Mental Healthcare Act, 2017* (MHCA) mandates equal access to healthcare goods, services and facilities for persons with mental illness.<sup>115</sup>

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<sup>111</sup> *Inspector (Mahila) Ravina v Union of India and Ors.*, (C) No. 4525/2014, order dt. 06.08.2015

<sup>112</sup> *Madhu and Anr. v Northern Railways & Or.* (2018) SCC Online Del 6660; *Lt. Col. Nitisha v Union of India* 2021 SCC Online SC 261

<sup>113</sup> *National Legal Services Authority v Union of India* (2014) 5 SCC 438

<sup>114</sup> *United India Insurance Ltd. v Jai Parkash Tayal* (2018) 247 DLT 349

<sup>115</sup> *Shikha Nischal v National Insurance Company Lt©* WP(C) No. 3190/2021, order dt. 19.04.2021

### ***Access to healthcare services in rural and tribal areas***

- Courts have given particular attention to the fulfilment of fundamental rights in rural and tribal areas.<sup>116</sup> In relation to healthcare, the Bombay High Court found that the government had an obligation under Article 21 to:
    - Appoint gynaecologists and paediatricians in rural and tribal districts which lack such personnel and healthcare services.
    - Provide hot cooked meals to tribal women, children and improve access to food security.
    - Appoint at least one Accredited Social Health Activist (ASHA) to provide home-based newborn and childcare in tribal districts in order to reduce infant mortality.
    - Improve working conditions of ASHAs and strengthen the programme.
    - Supply adequate antibiotics for treatment of infected new-borns and children for pneumonia.<sup>117</sup>
- iii. ***Acceptability*** requires that all healthcare goods, services and facilities must be respectful of medical ethics. In India, standards of informed consent are well-recognized in systems of statutory and common law (judge-made law) and are enforced by courts as seen in the cases highlighted below. Courts have also held that the privacy of medical data is protected by Article 21. This provision also forms the basis of reviews of public health interventions such as vaccine mandates and requires the government to balance public health interventions with Article 21 rights (informed consent, privacy, personal autonomy, bodily integrity). A violation is subject to judicial review; and, any restriction on Article 21 rights must satisfy the four-fold test: (i) State action must be sanctioned by statutory law, (ii) State action must be necessary in a democratic society for a legitimate aim, (iii) extent of interference must be proportionate to the achievement of object and (iv) provision of procedural safeguards against abuse of power. These principles have been applied in the decisions highlighted below.

### ***Requirement of specific, express consent for therapeutic procedures***

- On the issue of general consent versus specific consent for medical interventions, the Supreme Court has held that consent for a diagnostic test does not amount to consent for therapeutic procedure except in life threatening or emergency situations.
- If a patient is a competent adult and there is no medical emergency, it was found that there could be no question of substituted consent.
- Any unauthorized further medical procedure where there is no imminent danger to life or health of the patient, would give rise to a cause of action for medical negligence/battery.
- The court held that the correctness or appropriateness of the treatment procedure would not make the treatment lawful, in the absence of express consent for the treatment.<sup>118</sup>

### ***Informed consent in sterilization programmes disproportionately targeting women***

- The Supreme Court has held that persons undergoing sterilization must be explained the details of the procedure, its impact and consequences in the local language to obtain informed consent.
- Informed consent must be certified by a doctor as well as a trained counsellor.
- The court held that adequate time approximating an hour should be given to a patient to appropriately consider undergoing or refusing the sterilization procedure.
- Unsanitary and unethical sterilization procedures on women were found to mirror systematic societal discrimination against marginalized populations, when government programmes

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<sup>116</sup> *Kishen Pattanayak and Anr. v State of Orissa* AIR 1989 SC 677

<sup>117</sup> *Dr. Rajendra Sadanand Burma &Ors. v State of Maharashtra*, PIL No. 133/2007

<sup>118</sup> *Samira Koli v Dr. Prabha Manchanda* (2008) 2 SCC 1

should aim at remedying discrimination on basis of social and economic status and advancing substantive equality.<sup>119</sup>

#### ***Informed consent for Measles and Rubella (MR) vaccine for children***

- The Delhi High Court held that children cannot be vaccinated for MR forcibly or without consent.
- Opt-out consent was held to be impermissible. The Government was required to obtain affirmative consent of parents for vaccinating children by personally disseminating consent forms with appropriate information and collecting their responses.
- In case a parent does not respond in the stipulated period, their consent for the ward's/child's participation in the vaccine programme shall be presumed to be granted.
- Government was held to be obligated to provide parents information on (i) particulars of the vaccine proposed to be administered (ii) adverse side effects of the vaccine (iii) the date of administration of vaccine to the wards/children; and (iv) the personnel who would administer the same, in order to obtain informed consent for the vaccination.<sup>120</sup>

#### ***COVID-19 Vaccine Mandates***

- Based on existing medical evidence that unvaccinated individuals pose similar risk of transmission as vaccinated individuals, coercive vaccine mandates for COVID-19 that deny a range of services, resources and access to public spaces to unvaccinated individuals were held to be disproportionate measures that violate bodily integrity under Article 21 by the Supreme Court.
- In the event of risk to community health on review of medical evidence, governments may impose reasonable and proportionate restrictions on unvaccinated individuals.<sup>121</sup>

#### ***Privacy of medical records***

- The Supreme Court has held that health or medical data is an essential component of the right to privacy under Article 21, i.e., individuals have the right to control the extent of the government's access to such information.
- Legitimate interests of government with respect to disease surveillance must be balanced with the right to privacy of individuals.
- The government may access patient records to design public health interventions only if it preserves the anonymity of the individual.<sup>122</sup>

#### ***Bodily integrity/Personal autonomy***

- An advance directive by a person who is terminally ill or in a permanently vegetative state for withdrawing medical support or treatment was found to be an exercise of the right to bodily integrity under Article 21.<sup>123</sup>
- The forceful administration of narco-analysis tests, polygraph tests and brain electrical activation profile during a criminal investigation was held to violate the guarantee of personal autonomy under Article 21 against State interference.<sup>124</sup>

- iv. **Quality** requires that all healthcare goods, services and facilities must be scientifically and medically appropriate and of good quality. This includes skilled medical personnel, scientifically approved

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<sup>119</sup> *Devika Biswas v Union of India* (2016) 10 SCC 733

<sup>120</sup> *Master Hridaan Kumar (minor) And Ors. v Union of India and Anr.*, Writ Petition No. 343 of 2019

<sup>121</sup> *Jacob Puliyel v Union of India* 2022 SCC Online SC 533

<sup>122</sup> *Id* at 74, *Puttaswamy (I)*

<sup>123</sup> *Common Cause v Union of India* (2018) 5 SCC 1

<sup>124</sup> *Selvi v State of Karnataka* (2010) 7 SCC 263

drugs, hospital infrastructure etc. The cases below highlight the different manners of court intervention in this area including ensuring evidence-based treatment in national programmes, defining the contours of medical negligence and ensuring access to redressal and compensation for violations.

### ***Regulation of blood banks***

- In a PIL filed to bring to light serious flaws in the process of collecting, storing and supplying blood through various blood centres in India,<sup>125</sup> the court noted key concerns with U=unlicensed blood banks, lack of trained manpower at blood centres, unhygienic and inadequate storage conditions, and lack of medical testing and vulnerability of professional blood donors.
- The court stated that in view of the dangers inherent in supply of contaminated blood it must be ensured that blood that is available with blood banks is healthy and free from infection. It passed a series of directions, for immediate and long-term implementation, including:
  - Establishment of a National Council of Blood Transfusion by the Union Government, and similar bodies at the state/UT level, called 'State Councils.' The Councils would be responsible for looking into the entire range of services involved in operation of blood banks – launching campaigns to encourage voluntary blood donation, issuing technical protocols for proper collection, testing, storage, transport, and broadly for quality control of blood and blood components and training for human resources on the protocols.
  - The central and state governments had to ensure that within one year, all blood banks operating in the country are duly licensed, and thereafter all unlicensed blood banks should cease to operate through appropriate legal action.
  - The central and state governments were to take steps to eliminate professional blood donation within a period of two years.
  - Monitoring of the operation of the blood banks to be done through appointment and posting of adequate numbers of trained Drugs Inspectors.<sup>126</sup>

### ***Evidence-based treatment protocols***

- The Supreme Court considered a petition by a medical officer of the Revised National TB Control Programme (RNTCP), seeking to alter intermittent TB treatment (3 doses/week) to daily treatment, based on evidence of 5,300 patients who had multiple relapses after completing TB treatment.
- The court engaged with RNTCP and MOHFW officials, who, agreeing with the evidence on record, stated they need 9-12 months for staff training and procurement of drugs for national implementation of daily treatment.
- The court monitored the implementation of the revised treatment regimen until it was rolled out in October 2017.<sup>127</sup>

### ***Compensation***

- The Supreme Court held that patients are entitled to compensation after suffering irreversible damage due to negligence of medical personnel in a government health camp.<sup>128</sup>

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<sup>125</sup> Blood is treated as a 'drug' under the *Drugs and Cosmetics Act, 1940*, and regulations regarding equipment and supplies required for a blood bank are found in the *Drugs and Cosmetics Rules, 1945*.

<sup>126</sup> *Common Cause v Union of India* (1996) 1 SCC 753

<sup>127</sup> *Id* at 87, *Dr. Raman Kakkar*

<sup>128</sup> *S. Mittal v State of Uttar Pradesh* (1989) 3 SCC 223

- Courts have also awarded compensation to families in cases of avoidable deaths of pregnant women, who are compelled to travel far distances to access maternal healthcare services due to lack of adequately functioning PHCs in rural areas.<sup>129</sup>

#### **Consumer protection**

- Services rendered to patients by medical professionals (public or private; dispensaries, healthcare centres or dispensaries) by consultation, diagnosis and treatment (including surgical) have been held to be covered by the scope of services under consumer protection laws.<sup>130</sup>

### **2.4.2 Obligations to Respect, Protect, Fulfil the right to health**

- Respect:** The obligation to respect is multifarious in nature. Amongst other things, it limits the government from denying equal access for all persons to preventive, curative and palliative health services; abstaining from enforcing discriminatory practices as State policy; and prohibition on discriminatory practices relating to women's health. The cases highlighted below have a particular focus on how Indian courts have upheld sexual and reproductive rights, the recognition of the centrality of sexual and reproductive health rights to the right to health and the reliance on international treaties and norms.

#### **Survivors of gender-based violence**

- In view of Article 21, ICESCR and the UN Declaration of Basic Principles of Justice for Victims of Crime and Abuse of Power (1985), survivors of gender-based violence were held to be entitled to medical services with informed consent. As the two-finger test violates the right to informed consent, dignity and privacy of survivors of gender-based violence and constitutes cruel, inhuman and degrading treatment under international law, the government has been directed to take measures to prohibit such practices in medico-legal examination.<sup>131</sup>

#### **Access to abortion**

- A woman's right to make reproductive choices has been held to be a dimension of personal liberty as understood under Article 21. Reproductive choices extend to procreation as well as the choice not to procreate. No pregnant woman must be denied the facility of treatment at any stage irrespective of her social and economic background.<sup>132</sup>
- Right to sexual and reproductive health was also held to be an integral part of the right to highest attainable standard of physical and mental health guaranteed under Article 12 of ICESCR, as per General Comment No. 22 on sexual and reproductive health and rights read with CEDAW.<sup>133</sup>
- As registered medical practitioners (RMPs) across India were prohibited by the *Medical Termination of Pregnancy Act, 1971* (MTP Act) to perform abortions for women whose pregnancies were beyond the limitation period in order to prevent risk to physical or mental health of women or prevent carrying unviable pregnancies to term, the Supreme Court

<sup>129</sup> *State of Nagaland & Ors. v Moba Changkai and Anr.*(2021) 5 Gauhati Law Reports 272

<sup>130</sup> *Indian Medical Association v VP Shantha* (1995) 6 SCC 651, *Medicos Legal Action Group v Union of India*, PIL No. 58/2021, order dt. 25.10.2021

<sup>131</sup> *Lillu @ Rajesh and Anr. v State of Haryana* (2013) 14 SCC 643

<sup>132</sup> *Suchita Srivastava and Anr v Chandigarh Administration* (2009) 9 SCC 1

<sup>133</sup> *Z v State of Bihar and Ors.* (2018) 11 SCC 572

intervened in a series of cases and directed RMPs to perform abortions on the advice of medical boards constituted to advise the courts.<sup>134</sup>

- High Courts can, in exercise of jurisdiction under Article 226, permit women to undergo medical termination of pregnancy in event of risk to life, grave injury to woman's physical or mental health or foetal health risks as provided under the MTP Act even though the length of pregnancy is past the limitation period as per law. The High Court's permission for seeking abortion will be necessary where a woman's plea to terminate her pregnancy is placed within these conditions.
- In cases where a RMP feels that a termination of pregnancy is immediately necessary to save the life of a woman, there is no necessity for seeking the High Court's permission. It is the duty of a RMP to undertake the termination of pregnancy to prevent the death of a woman.<sup>135</sup>
- The Supreme Court has authoritatively declared that the MTP Act and Rules of 2003 (as amended in 2021) must be applied by RMPs in a manner that factors every material change in women's circumstances that presents a decision to seek abortion. As such, the court has declared that the framework of medical termination of pregnancy must be accessible for single women, transgender and gender non-conforming individuals who need such services.<sup>136</sup>

### **Maternal health**

- Verification of social and economic background or insistence on providing documentation to prove BPL status for eligibility to access benefits should not act as a barrier to accessing health services under Janani Suraksha Yojana (JSY).<sup>137</sup>
- The right to health under Article 21 has been held to be instilled with rigours of right to health obligations under ICESCR, General Comment 14 and CEDAW, which are legally enforceable in India by virtue of the PHRA.
- Central and Delhi governments have been directed to recruit adequate numbers of auxiliary nursing mid-wives and ASHAs to ensure access to the full range of sexual and reproductive healthcare services for women during COVID-19.<sup>138</sup>
- The right to reproductive health has been held to be guaranteed under Article 21, ICESCR and CEDAW and includes identification of high risk pregnancies, followed by prompt referral cases needing specialist care, reducing stillbirth rates and infant mortality, adequate health facilities for providing pre-natal as well as post-natal care for women, making available trained medical workers, medical equipment, medicines, blood supplies and other requisites at public hospitals and CHCs for their proper functioning are indefeasible components of reproductive rights.<sup>139</sup>
- On a plea of violation of Articles 14, 15 and 21 for failure to provide for provision of reproductive and child health services and elderly care under NRHM programmes like JSY and Janani-Shishu Suraksha Karyakram (JSSK), directions were issued to the Sikkim government to ensure availability of life-saving drugs, implementation of JSY and JSSK, regularly conducting Maternal Death Reviews and Community Based Monitoring for uploading on National Health Mission website, among other directions.<sup>140</sup>

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<sup>134</sup> *X v Union of India* (2016) 4 SCC 382, *Meera Santosh Pal v Union of India* (2017) 3 SCC 462, *Sarmishtha Chakraborty v Union of India* (2018) 13 SCC 339, *Tapasya Umesh Pisal v Union of India* (2018) 12 SCC 57

<sup>135</sup> *XYZ v Union of India* (2019) 3 Bom CR 400

<sup>136</sup> *X v Principal Secretary, Health and Family Welfare Department, Govt. of NCT of Delhi* 2022 SCC Online SC 1321

<sup>137</sup> *Id* at 16, *Laxmi Mandal*

<sup>138</sup> *SAMA Resource Group for Women and Health v Union of India*, WP (C) No. 2983 of 2020, order dt. 22.04.2020

<sup>139</sup> *Kali Bai v Union of India* AIR 2018 (NOC 695) 242

<sup>140</sup> *Rinzing Chewang Kazi v State of Sikkim* 2016 SCC Online Sikk 38



- The implementation of maternity benefits, including payment of wages and childcare leave, must be implemented in a purposive manner which affords women the autonomy to lead fuller lives as parents as well as workers.<sup>141</sup>

### ***Essential drugs for maternal health***

- A batch of petitions by private drug manufacturers and health groups challenged the validity of a 2018 notification under the *Drugs and Cosmetics Act, 1940* that banned the essential drug *oxytocin* (used to prevent and treat post-partum haemorrhage (PPH) used to induce labour and for abortion) for domestic manufacture and distribution, which would endanger lives of pregnant women and young mothers.
- *Oxytocin* is classified as an essential drug by the WHO as well as included in the National List of Essential Medicines (NLEM) as per the Drugs (Prices) Control Order, 2013. The petitioners argued that PPH is the leading cause of maternal mortality, and therefore the drug serves vital primary healthcare needs.
- The petitioners submitted that as *oxytocin* is also approved and recommended for veterinary use among cattle for stemming PPH, it can be misused by administering to cattle for inducing easier lactation in the dairy industry; however, as the State agencies issued an overbroad ban for human use because they failed to curb misuse by monitoring sale records of pharmacists, it was submitted the impugned notification was arbitrary and violated Article 14 and violated the right to trade under Article 19(1)(g) as an unreasonable restriction.
- The court found that the sole public sector undertaking identified by the government to manufacture *oxytocin* was grossly under-funded and under-equipped to manufacture the essential drug, therefore, a complete ban on private manufacturers would deprive pregnant women and young mothers the therapeutic value of the essential drug and violate their right to health under Article 21 read with Article 47. The notification failed to satisfy the standard of proportionality as the authorities failed to balance the competing interests; the court quashed it, declaring it unconstitutional.<sup>142</sup>

### ***LGBT health***

- In relation to criminalization of same-sex relationships, the Supreme Court held that:
  - Section 377, IPC forced consensual sex between adults into the realm of fear and shame, as persons who engaged in oral and anal sex risk criminal prosecution if they seek health advice. This impeded their realization of the highest attainable standard of physical and mental health under Article 21.
  - The definition of mental illness as per the MHCA, which requires determination of mental illness on basis of national as well as internationally accepted medical standards (including latest versions of the International Classification of Diseases by the WHO) makes evident that homosexuality is not to be treated as a mental illness, contrary to older regimes of medical knowledge.
  - Counselling practices will have to focus on providing support to homosexual clients to become comfortable with who they are, rather than motivating them to change. The medical profession must share the responsibility to help individuals, families, educational institutions and workplaces to understand sexuality completely to create a society free from discrimination.
  - Yogyakarta Principles (YP), which establish international human rights standards and their application to sexual orientation and gender identity issues are made applicable by courts to give content to fundamental rights under Article 14, 15, 19 and 21 of the Constitution.

<sup>141</sup> *Deepika Singh v Central Administrative Tribunal 2022 SCC Online SC 1088*

<sup>142</sup> *BGP Products Operations and Ors. v Union of India, WP(C) No. 6084/2018*

- As per Principle 17 of YP, everyone has the right to the highest attainable standard of physical and mental health, without discrimination based on sexual orientation and gender identity.<sup>143</sup>
  - In another case the court directed the National Medical Commission (NMC) to review existing medical curriculum and research for medical students and personnel to respond to healthcare needs of the LGBT community.<sup>144</sup>
- ii. **Protect:** The obligation to protect contains several aspects, including India’s duty to adopt legislation or to take other measures ensuring equal access to health-related services provided by third parties. This duty covers a range of issues related to the regulation of the private sector too. Judicial approaches to this issue are covered in detail in Section 3 of this paper. Apart from requiring that medical practitioners and other healthcare professionals meet appropriate standards of education and ethical conduct, it also obliges the government “to prevent non-state actors from coercing women to undergo traditional practices, e.g., female genital mutilation; and to take measures to protect vulnerable groups, in particular women, minors and older persons, in the light of gender-based violence.”<sup>145</sup> Some of the cases that have arisen in this context are discussed here.

#### **Intersex healthcare**

- The Tamil Nadu government was directed to issue a government order for prohibition of forced corrective surgeries on intersex infants and children to respect self-determination of gender identity on basis of Articles 15, 19 and 21.<sup>146</sup>
- The Delhi High Court issued a similar decision and directed the NCT of Delhi government to prohibit forced corrective surgeries on intersex infants and children.<sup>147</sup>

#### **Conversion therapy**

- The Madras High Court directed NMC to take steps for prohibition of conversion therapy and take disciplinary action against healthcare professionals who provide such unscientific and harmful services.
- The NMC has amended the *Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 (MCI Ethics Regulations)* to classify conversion therapy as a ‘professional misconduct’ and authorized ‘State Medical Councils’ to take action against medical practitioners on complaint of violations.
- The MOHFW and Ministry of Women and Child Development (MWCD) was directed to train ASHAs on healthcare services for transgender persons.<sup>148</sup>
- On the other hand, the Kerala High Court directed the constitution of an expert committee to frame guidelines to ban ‘forced’ conversion therapy, to be produced before it on next hearing.<sup>149</sup>
- While the Madras High Court’s intervention in response to conversion therapy was rights-based, the Kerala High Court’s intervention was not; it failed to unqualifiedly prohibit the practice of conversion therapy, with anything short of such a measure exposing LGBT persons to gross rights violations.

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<sup>143</sup> Id at 83, *Navtej Singh Johar*

<sup>144</sup> *Queerhythm v National Medical Commission &Ors.*, WP(C) No. 18210/2021, order dt. 07.09.2021

<sup>145</sup> Id at 12, *General Comment 14*

<sup>146</sup> *Arunkumar and Anr. v Inspector General of Registration &Ors.*, AIR 2019 Mad 265

<sup>147</sup> *Srishti Madurai Educational Research Foundation v Govt. of NCT of Delhi*, WP(C) No. 8967/2021, order dt. 27.07.2022

<sup>148</sup> *Sushma and Anr. v Commissioner of Police*, WP No. 7284 of 2021, orders dt. 07.06.2021, 17.02.2022 and 02.09.2022

<sup>149</sup> *Queerala v State of Kerala*, WP (C) No. 21202/2020, order dt. 10.12.2021

### **Clinical Trials**

- The Supreme Court's intervention regarding unethical practices in vaccine trials led to deliberations within the government on strengthening the regulatory framework on clinical trials in India.<sup>150</sup> This eventually led to the passing of the *New Drugs and Clinical Trials Rules, 2019* under the *Drugs and Cosmetics Act, 1940* which seek to balance the scientific need for developing new drugs with the health and well-being of human participants in trials.
- iii. **Fulfil:** The obligation to fulfil requires that India give recognition to the right to health through laws and policies. As seen below, despite the separation of powers, constitutional courts have recommended that the executive frame policy and monitored developments to ensure access to treatment and medicines for rare diseases. As noted earlier, while some obligations such as access to essential drugs form core obligations that require immediate steps to be taken, the right to health is generally subject to progressive realisation. There is clear recognition of this approach in court decisions as well.

### **COVID-19**

- The Madras High Court directed that persons with disabilities be prioritized for vaccination and the state government ensure that vaccine centres are accessible by constructing ramps and other measures in accordance with the RPD Act.<sup>151</sup>
- The Bombay High Court directed the state government to provide testing and personal protective equipment (PPE) for all frontline workers in healthcare facilities (public and private), that facilities must increase capacity of ventilators and ambulances and to maintain a COVID-19 War Room Dashboard for citizen's right to information on the public health status as well as availability of healthcare goods, services and facilities in the state to fulfil its obligation under Article 21.<sup>152</sup>
- In Manipur, the High Court directed that if the state government does not have adequate funds for responding to COVID-19, it must request the central government for funds, and the central government shall consider generating additional funds either by increasing the existing rate of taxes or by introducing a new tax specifically for responding to the public healthcare emergency.<sup>153</sup>
- The Telangana High Court passed directions to ensure that the transgender community has access to food security, HIV-related healthcare services, gender affirmative healthcare services and social security.<sup>154</sup>
- In order to prevent the spread of COVID-19 in custodial settings, the Supreme Court issued directions to various bureaucrats in all states and UTs to adopt immediate measures in providing medical assistance to prisoners,<sup>155</sup> children<sup>156</sup> and women<sup>157</sup> in such settings and ensure their well-being.

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<sup>150</sup> *Swasthya Adhikar Manch v Union of India & Ors.*, WP(C) No. 33/2012. See also *Kalpna Mehta v Union of India & Ors.*, WP(C) No. 558/2012 wherein the court monitored an enquiry on allegations of unethical vaccine trials for Human Papilloma Virus (HPV) in States of Gujarat and Andhra Pradesh among 24,000 tribal girls in 2012

<sup>151</sup> *Meenakshi Balasubramanian v Union of India*, W.P. No 2951/2021, order dt. 19.04.2021

<sup>152</sup> *Jan Swasthya Abhiyan v State of Maharashtra*, 2020 SCC Online Bom 713

<sup>153</sup> *J. Hillson Angam v State of Manipur*, 2020 SCC Online Mani 150; *State of Manipur v. J. Hillson Angam*, SLP (C) No. 7801/2021, order dated 06.09.2021

<sup>154</sup> *Vyjayanti Vasanta Mogli v State of Telangana*, WP (PIL) No. 74 of 2020

<sup>155</sup> *Contagion of Covid-19 Virus in Prisons, In re*, (2020) 5 SCC 313

<sup>156</sup> *Contagion of Covid-19 Virus in Children Protection Homes, In re*, (2020) 15 SCC 280

<sup>157</sup> *Rishad Murtaza v Union of India*, (2020) 15 SCC 288

- The Supreme Court directed all states to issue a uniform policy ensuring that while preventing spread of COVID-19, Anganwadi Centres (AWC) and other schemes for providing nutritional food to children, nursing and lactating mothers are not adversely affected.<sup>158</sup>
- The Supreme Court oversaw the crisis related to migrant labour exodus during the national lockdown, and issued directions to state governments to provide access to food and water supply, medical testing and transportation for labourers travelling to home states.<sup>159</sup>

**Directions to frame policies: treatment for rare diseases**

- Access to life-saving medicines for rare diseases has been held to be a non-derogable component of the right to health under Article 21 and ICESCR and General Comment 14.
- The Delhi High Court suggested the MOHFW consider framing a policy on rare diseases.<sup>160</sup> In subsequent petitions on access to treatment for rare diseases, the court monitored the finalization of the *National Policy for Rare Diseases, 2021* by the MOHFW under previous orders passed on basis of Article 21 and the obligation to fulfil the right to health according to General Comment 14.<sup>161</sup>

**Core obligations: access to life saving multi-drug resistant Tuberculosis (MDR-TB) medicines**

- The Petitioner sought a direction from the Delhi High Court to the hospital to conduct a drug sensitivity test for his daughter living with MDR-TB and provide treatment with *bedaquiline*, as prescribed by her treating doctor. However, as the test would take 4-6 weeks, the petitioner further submitted that since his daughter is critically ill, they are willing to have the drug administered without tests, on advice of a TB specialist. The court directed the hospital to correspond with the TB specialist and decide on appropriate treatment.
- After initial reluctance due to RNTCP protocols related to domicile status of patients, the hospital stated that it would provide treatment to the patient with *bedaquiline* and other drugs.
- The Petitioner further prayed that another drug *delamanid* is also necessary for the patient's treatment, and will be making an application for conditional access as it is not available in India.
- The court directed the Drug Controller General of India (DCGI) to process the petitioner's application for conditional access on an urgent basis.
- The hospital clarified that domicile status of a patient will no longer be relevant criteria in access to the drug under the conditional access programme.<sup>162</sup>

**Progressive realization of the right to health: HIV related healthcare**

- Universal access to anti-retroviral (ARV) drugs, CD4 diagnostic kits, treatment for opportunistic infections, district-level ARV treatment centres etc. has been held to be an essential component of Article 14 and Article 21.
- Over several years, the Supreme court gave regular directions for ensuring availability of healthcare facility-level grievance redress systems, personal protective equipment (PPE) for healthcare workers, training and sensitization of general healthcare personnel with National

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<sup>158</sup> *Closure of Mid-Day Meal Scheme, In re*, (2020) 12 SCC 213; *Dipika Jagatram Sahani v Union of India* 2020 SCC OnLine SC 1070

<sup>159</sup> *Problems & Miseries of Migrant Labourers, In re*, (2020) 7 SCC 231

<sup>160</sup> Id at 60, *Mohd. Ahmed (minor)*

<sup>161</sup> *Baby Devananda (through mother) v Employees State Insurance Corporation*, 2017 SCC Online Del 12779; *Master Arnesh Shaw v Union of India*, WP (C) No. 5315/2020, order dt. 04.02.2021

<sup>162</sup> *Kaushal Kishore Tripathi v Lal Swarup TB Hospital*, WP(C) No. 11879/2016

AIDS Control Organization (NACO) protocols, rationalization of treatment in private sector and scaling-up availability of HIV-related healthcare goods, services and facilities.<sup>163</sup>

- The process of a 'continuing mandamus' by constitutional courts is a practical strategy to ensure progressive realization of health, as the Supreme Court did in this case.

### **2.4.3 Social/underlying determinants**

A key component of the right to health is the obligation of governments to ensure access to underlying determinants of health. As just one example, Dalit women face higher risk of mortality due to poor access to sanitation, water supply and healthcare, resulting in 14.6 years shorter lifespan compared to upper caste women on average,<sup>164</sup> underscoring the need to address social inequalities in health. The centrality of these determinants of health to the right to health have been recognised by the Indian courts as the selection of cases below shows.

#### **Public toilets**

- Access to public toilets affects everybody, however, they impact women uniquely. Women have less than half of the public services available for men in public spaces. Women often combine childcare and home-maker responsibilities, in addition to professional labour, which results in travel needs which are qualitatively different to men's work and travel. Access to public toilets is felt even more acutely due to menstrual healthcare needs of women, in addition to women comprising a large proportion of primary caregivers for the elderly, persons with disabilities, children, which increases their burden of making supplementary trips to a restroom.
- Article 12 of ICESCR and Article 21 of the Constitution mandates that the right to health includes underlying determinants of health, like access to public toilets and sanitation facilities.
- The Bombay High Court issued directions to all municipal corporations in Maharashtra with respect to upgrading existing facilities as well as construction and maintenance of new public toilets and sanitation facilities.<sup>165</sup>

#### **Water supply**

- Holding that residents of informal settlements cannot be deprived of the fundamental right to water under Article 21 on the ground that they are in unlawful occupation of public lands, the Bombay High Court issued directions to the municipal corporation to frame policy to supply water to residents of informal settlements.<sup>166</sup>
- The Supreme Court has held that there is a direct link between water and human survival, and effective water management is part of sustainable development as water is a finite resource. All regulatory authorities were directed to bear in mind the water demand of any development project during granting permissions, and such analysis must be an essential part of the decision-making process.<sup>167</sup>

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<sup>163</sup> *Sankalp Rehabilitation Trust v Union of India*, WP (C) No. 512/1999, orders dt. 01.10.2008, 11.12.2012 and 02.12.2013

<sup>164</sup> Borooah, VK et al (2012), Gender and Caste based Inequality, in Health Outcomes in India, Working Paper Series VI (03), New Delhi, Indian Institute of Dalit Studies

<sup>165</sup> *Milun Saryajani & Ors. v Pune Municipal Commissioner & Ors.*, 2015 SCC Online Bom

<sup>166</sup> *Pani Haq Samiti v Brihan Mumbai Municipal Corporation*, PIL No. 10 of 2012, order dt. 15.12.2014

<sup>167</sup> *Betqui Candola Samvardhan Samitee v Gera Developments Pvt. Ltd.* (2019) 4 Mh.L.J.92

### **Food Security**

- The fundamental right to food is guaranteed by Article 21 read with Article 39(a)<sup>168</sup> and Article 47, therefore, government schemes providing access to food security like Antyodaya Anna Yojana (AAY), Mid-Day Meals (MDM), ICDS and others have been held to be constitutionally protected rights.<sup>169</sup>
- State governments were found to be entitled to provide food rations *over and above* to the entitlements guaranteed under the *National Food Security Act, 2013* (NFSA), like edible oils and dal/lentils, during crises like droughts.<sup>170</sup>
- High Courts have issued directions to ensure proper implementation of health schemes devised to reduce infant and maternal mortality, on the basis that the right to maternal health is inseparable from the right to food as a social determinant of health.<sup>171</sup>
- On hiring service providers for AWCs, the Supreme Court has recommended the decentralization of the ICDS programme by hiring local women's self-help groups (SHGs) who can provide hot cooked meals at the AWCs, proven to be of high nutritional value, in comparison to private, industrial contractors who provide ready-to-cook food which is of poor nutritional value. The principal function of the ICDS is to prevent malnutrition related deaths, and food commissioners have documented the successes of hiring local women's SHGs in achieving this goal.<sup>172</sup>
- Reiterating that the right to food is a part of Article 21, the Allahabad High Court held that food preferences which are conducive to one's health cannot be treated as wrong or unlawful. Diverse cultural practices and food preferences as part of India's secular society, socio-economic status of sections of society involved in the beef trade, the availability of meat at affordable price – all were held to be relevant issues of constitutional importance which need to be factored in when a government decides to liberalise, regulate or prohibit slaughterhouses.<sup>173</sup>

### **Adequate housing**

- The right to housing has been held to be a bundle of rights which is not limited to just shelter and extends to the rights to livelihood, health, education food as well as the right to clean drinking water, sanitation and transport facilities.
- The 'right to the city' acknowledges people living in *jhuggi-jhopri bastis* as equal participants and contributors to the social and economic life of the city. These include sanitation workers, garbage collectors, domestic help, public transport drivers, labourers and a wide range of service providers indispensable to a city. Prioritizing the housing needs of this population was held to be imperative for a State committed to social welfare; these obligations were found to flow from the ICESCR and the Constitution.
- The constitutional position on housing discourages a narrow view of a dweller in a *jhuggi-jhopri basti* as an 'illegal occupant without rights.' The right to adequate housing was thus held to amount to a right to access several aspects that protect the capability of a person to exercise the freedom to live in a city. Such individuals were recognised as rights bearers whose constitutional rights must be recognised, protected and enforced.<sup>174</sup>

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<sup>168</sup> Article 39(a): *The State shall, in particular, direct its policy towards securing that the citizens, men and women equally, have the right to an adequate means to livelihood*

<sup>169</sup> Id at 57, *PUCL interim order* dt. 28.11.2001

<sup>170</sup> *Swaraj Abhiyaan v Union of India*, (2016) 7 SCC 498

<sup>171</sup> Id at 10, *Laxmi Mandal*

<sup>172</sup> *Vaishnorani Mahila Bachat Gat v State of Maharashtra & Ors.* (2019) 15 SCC 718

<sup>173</sup> *Mohd. Mustafa & Ors. v Union of India* (2017) 5 All LJ 275

<sup>174</sup> *State of Maharashtra v Charudutta Pandurang Koli & Ors.* 2019 SCC Online Bom 1993; *Ajay Maken & Ors. v Union of India* (2019) 260 DLT 581

### **Environment and Climate Change**

- The Supreme Court has held that Articles 38 and 47 mandate that municipal corporations perform the public health function of preparing action plans to address sewage treatment.<sup>175</sup>
- Holding that Article 21 establishes an inextricable link between the right to a pollution-free environment and the right to health, the Bombay High Court found that solid waste management protocols must be implemented by waste generators, urban local bodies, village panchayats and pollution control committees to ensure a pollution-free environment for everyone.<sup>176</sup>
- The courts have intervened and issued orders to close operations of industries causing air pollution and loss of ecology by declaring that Article 21 includes the right to protect and preserve the environment to ensure a healthy life; therefore, development plans must demarcate zones for industrial use to reflect the need to maintain ecological balance.<sup>177</sup>
- In the originalist era, courts did not deem it fit to exercise jurisdiction in petitions seeking directions to government to take efforts to respond to the *effects* of climate change.<sup>178</sup> However, the Delhi High Court recently exercised its jurisdiction to hear a petition filed to seek constitution of a committee of eminent jurists and technical experts to propose suggestions for taking action, including legislative amendments to realize the commitments made by the Indian government under the 2021 United Nations Framework Convention on Climate Change (UNFCCC). The court was informed that a Prime Minister’s Council on Climate Change has been constituted, and after directions were issued for the government to file a status report, detailed submissions were filed by the government on the decisions, initiatives and committees responding to various aspects of the UNFCCC. The court noted its appreciation for the actions being taken by the government on a “war-footing” even as the petitioner agreed that no further orders were required given the detailed response of the government.<sup>179</sup>

The scope of substantive directions issued by constitutional courts in the aforementioned cases irrefutably and affirmatively settles the concern over the enforceability of the right to health due to its lack of explicit recognition under the Constitution. As these cases amply demonstrate, the right to health in all its facets and dimensions is a fundamental and justiciable right under Article 21.

### **3. COURT INTERVENTIONS IN KEY AREAS OF HEALTH**

This section of the paper discusses court intervention in two key areas that are of particular interest in UHC debates in India. The first relates to central and state governments’ jurisdiction over health matters. As evidenced by COVID-19, the division of responsibilities posed challenges to the efforts of governments at both levels to coordinate an appropriate response during the pandemic. Resolving these challenges will be essential in ensuring the delivery of UHC in India. Starting with a brief overview of the framework of distribution of powers between both levels of government under the Constitution, the first part of the inquiry proceeds to review a selection of cases on public health that clarify their roles to act in a spirit of cooperation. The second area of inquiry relates to the regulation of the private health sector. Given the outsized role of the private sector in healthcare delivery in India and the likelihood that the private sector will play a role in UHC, how courts have intervened in this area is important to understand. The second

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<sup>175</sup> *Municipal Council, Ratlam v Vardichand & Ors.* AIR 1980 SC 1622

<sup>176</sup> *Vijay Laxmanrao Dak v Union of India* (2018) 5 Bom CR 513

<sup>177</sup> *Rural Litigation and Entitlement Kendra v Dehradun v State of Uttar Pradesh* AIR 1985 SC 652; *T. Damodar Rao v Special Officer, Municipal Corporation of Hyderabad* AIR 1987 SC 171

<sup>178</sup> *Vijay Mehta v State of Rajasthan* AIR 1980 Raj 207

<sup>179</sup> *Rohit Madan v Ministry of Env't., Forests and Climate Change (MoEFCC)*, WP (C) No. 6319/2022

part of this section reviews judicial developments related to different parts of the healthcare architecture in India.

### **3.1 Centre-state relations and the right to health**

This section provides a brief overview of the distribution of legislative and administrative powers between the central and state governments as per the Constitution, before examining how judicial interventions in matters of health assign responsibilities in accordance with this power-sharing arrangement.

#### **3.1.1 Framework of centre-state relations under the Constitution**

Chapter 1 of Part XI of the Constitution sets forth the manner in which legislative powers are distributed between the central and state governments. Article 245 prescribes the territorial jurisdiction of Parliament as the whole or any part of India and of 'State Legislatures' as the whole or any part of the State.

Article 246, referencing Schedule VII which contains three lists (Union, State and Concurrent Lists), provides the scheme of distribution of legislative powers. Article 246(1) confers exclusive powers on Parliament to make laws on subjects under List I (Union), Article 246(3) confers exclusive powers on state legislatures to make laws on subjects under List II (State), and Article 246(2) empowers both Parliament and the state legislatures to make laws on subjects under List III (Concurrent) of Schedule VII. The powers of state legislatures under Article 246 are expressly subject to those of Parliament in cases of irreconcilable overlap or conflict between the Lists.

Article 248 read with Entry 97 of List I vests residuary powers with Parliament with respect to matters not included in List II and List III. The *Commissions of Enquiry Act, 1952* was enacted by Parliament by exercising authority under this provision, giving the Central Government the power to constitute a commission for enquiry into matters of public importance with respect to matters provided under all three Lists. However, courts have held that the residuary powers must be narrowly interpreted to protect autonomy of the states. If there is a conflict between a state law based on List II and a central law based on Entry 97 of List I, the power in the state List must be given a broad and plentiful interpretation to uphold the state law and respect the principle of federalism.<sup>180</sup>

Central legislations on health have been passed under two important provisions of the Constitution. Under Article 252, if two or more states consent by passing a resolution in the legislature, Parliament may make laws for any matter within the state List to be applicable to such states, and other states may also adopt such a law in like manner. The CEA is an example of this legislative process, where legislatures of Arunachal Pradesh, Himachal Pradesh, Mizoram and Sikkim passed such resolutions, thereby authorizing Parliament to make the law. The CEA has been challenged by medical practitioners on grounds of the central government's lack of legislative competence to enact a law in the backdrop of state-level laws to regulate the private sector. However, courts have defended the constitutional validity of the central government exercising its power under Article 252.<sup>181</sup> The *Transplantation of Human Organs Act, 1994* was also enacted by Parliament under this authority as legislatures of Himachal Pradesh, Maharashtra and Goa passed similar resolutions.

Under Article 253, Parliament has the power to make any law to give effect to a treaty, international agreement or convention, notwithstanding the fact that the subject matter of the law may have been

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<sup>180</sup>*International Tourist Corpn. v State of Haryana* (1981) 2 SCC 318

<sup>181</sup>*Dr. Ashwini Goyal v Union of India*, WP (C) 3490/2012, order dt. 31.07.2012



listed under the State List. The *Bhopal Gas Leak Disaster (Processing of Claims) Act, 1985*, the HIV Act, the MHCA and the RPD Act are all examples of this legislative process. The implementation of some of these health-related laws and any centre-state issues are highlighted in Working Paper 3 in this series.

The Constitution details a few additional circumstances where Parliament may make laws on matters under List II. This includes where the Rajya Sabha passes a resolution with a two-thirds majority that it is essential in 'national interest,'<sup>182</sup> or when a proclamation of emergency is in effect.<sup>183</sup>

Article 254 resolves conflicts between parliamentary and state laws. Article 254(1) provides that if a state law is repugnant to a parliamentary law, the parliamentary law will prevail and the state law will be void to the extent of the repugnancy, whether the parliamentary law was passed before or after the state law. Article 254(2) provides that if a state law relating to powers under List III (Concurrent) contains a provision that is repugnant to a parliamentary law, the law will be applicable in the state on receiving the President's assent. The *Prevention of Cruelty to Animals (Tamil Nadu Amendment) Act, 2017* is an example of this legislative process.

Courts have held that where a state law, while being substantially within the scope of the powers in the state List, encroaches upon any of the powers in the central List, the *doctrine of pith and substance* must guide the assessment of constitutional validity of the state law. The state law must be upheld, if on an analysis of the scheme of both laws it appears that by and large the subject matter of the law falls within the four corners of the state List and impinges on central powers incidentally. However, if the conflict between central and state laws is substantially irreconcilable, the central law prevails and the state law will be void to the extent of the repugnancy.<sup>184</sup>

Courts have also held with respect to distribution of powers between the centre and state that a state law based on a 'general' power in List III (*Concurrent: Entry 25 – Education, including technical education, medical education and universities, subject to the provisions of Entries 63, 64, 65 and 66 of List I; vocational and technical training of labour*) is subject to the centre's power to make law on a 'specific' power under List I (*Union: Entry 66 – Co-ordination and determination of standards in institutions for higher education or research and scientific and technical institutions*), especially when the general power is qualified expressly in relation to the centre's specific power.<sup>185</sup>

Chapter 2 of Part XI of the Constitution sets forth the division of executive powers between the centre and the states, which largely parallels the distribution of legislative powers between them. As per Article 73, the executive power of the centre extends to all such matters on which Parliament has the power to make laws. Similarly, as per Article 162, states may exercise their executive powers only within the ambit of their legislative powers, subject to the centre's power under List III. The state's executive power must comply with the laws passed by Parliament and other laws applicable in the state, and to effect that, the central government may give directions to states.

With respect to legislative and administrative powers directly or tangentially related to matters of health and social determinants, key entries are reproduced in the box for illustration.

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<sup>182</sup> Article 249 of the Constitution of India.

<sup>183</sup> Article 250 of the Constitution of India. See also Article 251 which states that if there is inconsistency between a Parliamentary law under Articles 249 and 250 and a state law, Parliamentary law will prevail, whether passed before or after the state law, and the state law shall to the extent of the repugnancy give way, until Parliamentary law continues to have effect.

<sup>184</sup> *M. Karunanidhi v Union of India and Anr.* (1979) 3 SCC 431

<sup>185</sup> *Prof. Yashpal v State of Chhattisgarh* (2005) 5 SCC 420

**Box: Key Entries Related to health in the Union, State and Concurrent Lists  
in Schedule VII of the Constitution of India**

**List I – Union**

- Entry 13: Participation at international conferences, bodies and implementing decisions
- Entry 28: Port quarantine, including hospitals connected therewith; seamen's and marine hospitals
- Entry 42: Inter-state trade and commerce
- Entry 47: Insurance
- Entry 55: Regulation of labour and safety in mines and oilfields
- Entry 63: Institutions like Benaras Hindu University, Aligarh Muslim University and the Delhi University; any other institution declared by Parliament by law to be an institution of national importance
- Entry 64: Institutions for scientific and technical education financed by the Govt. of India wholly or in part and declared by Parliament by law to be institutions of national importance
- Entry 65: Union agencies and institutions for:
  - (a) professional, vocational or technical training, including the training of police officers, or
  - (b) promotion of special studies or research, or
  - (c) scientific or technical assistance in the investigation or detection of crime
- Entry 66: Co-ordination and determination of standards in institutions for higher education or research and scientific and technical institutions.
- Entry 81: Inter-state migration and inter-state quarantine
- Entry 97: Any other matter not enumerated in List II or List III

**List II – State**

- Entry 6: Public health and sanitation; hospitals and dispensaries
- Entry 9: Relief of the disabled and unemployable
- Entry 14: Agriculture, including agricultural education and research, protection against pests and prevention of plant diseases
- Entry 15: Preservation, protection and improvement of stock and prevention of animal diseases, veterinary training and practice
- Entry 17: Water, that is to say, water supplies, irrigation and canals, drainage and embankments, water storage and water power subject to the provisions of entry 56 in List I

**List III – Concurrent**

- Entry 8: Actionable wrongs
- Entry 16: Lunacy and mental deficiency; including places for the reception or treatment of lunatics and mental deficient
- Entry 18: Adulteration of foodstuffs and other goods
- Entry 19: Drugs and poisons, subject to provisions of entry 59 of List I with respect to opium
- Entry 20: Economic and social planning
- Entry 20-A: Population control and family planning
- Entry 23: Social security and social insurance; employment and unemployment
- Entry 24: Welfare of labour including conditions of work, provident funds, employer's liability, workmen's compensation, invalidity and old age pensions and maternity benefits
- Entry 25: Education, including technical education, medical education and universities, subject to provisions of entries 63, 64, 65 and 66 of List I; vocational and technical training of labour
- Entry 26: Legal, medical and other professions
- Entry 29: Prevention of extension from one State to another of infectious or contagious diseases or pests affecting men, animals or plants
- Entry 30: Vital statistics including registration of births and deaths
- Entry 34: Price control

Despite the division of powers, conflicts between the centre and states arise frequently, usually ending up at the door of the Supreme Court. The courts have clearly recognized the importance of the jurisdiction and powers of state governments holding that they are constitutionally recognized units and not administrative divisions, as both the centre and the states are formed by the Constitution. State governments have an independent constitutional existence and they have as important a role to play in the social, economic and political life of the people as the central government.<sup>186</sup>

Still, as also noted by the courts, there is no precise bifurcation in the administration of central and state laws in India. State officials administer state laws as well the central laws applicable within that state, whereas central bureaucratic appointees while working within a state, also carry out state laws, insofar as they may be applicable.<sup>187</sup> Adopting the doctrine of *cooperative federalism*, constitutional courts have declared that central and state governments must negotiate and coordinate in their related duties, as the Constitution is fundamentally federal in conception.<sup>188</sup>

The recommendations of the Finance Commission (a constitutional body under Article 280) are instructive in shaping fiscal federalism in India as it determines cost-sharing between central and state governments. In 2020, the XVth Finance Commission noted that 70 percent of public expenditure on health is borne by states and only 30 percent is shared by the central government.<sup>189</sup> In terms of disaster related grants, the Finance Commission has recommended allocation of financial resources between the central and state governments in a 75:25 ratio for general states and 90:10 for northeast and Himalayan states.<sup>190</sup> In the matter of payment of *ex gratia* compensation by government to families of persons who died on account of COVID-19, the Supreme Court directed the Central Government to frame guidelines under the *Disaster Management Act, 2005* (DMA) for mitigation and relief measures on basis of this recommendation of the Finance Commission on allocation of financial resources.<sup>191</sup>

### **3.1.2 Judiciary-Executive interface in Centre-State relations in areas of health law, policy and programmes**

The interplay of negotiation and coordination between central and state governments is demonstrable in judicial interventions in matters related to public health. A review of litigations focused on public health which explicitly implicate the questions of centre-state demarcation of responsibility, reveals that constitutional courts are currently dealing with cases relating to state-level compliance of central guidelines on medico-legal care for survivors of sexual violence,<sup>192</sup> state-level adoption of laws regulating clinical establishments,<sup>193</sup> central-state collaboration on undertaking public health measures (legislative and/or administrative) to regulate the private sector<sup>194</sup> and state-level implementation of the *Ayushman Bharat Pradhan Mantri Jan Aarogya Yojana* (AB-PMJAY) health insurance scheme.<sup>195</sup> However, as these cases are at the initial stages of issue of notice or seeking status reports from the central and state governments, they do not provide any insights yet. These cases must be tracked for developments.

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<sup>186</sup> *National Capital Territory of Delhi v Union of India* (2018) 8 SCC 501

<sup>187</sup> *Bir Singh v Delhi Jal Board* (2018) 10 SCC 312

<sup>188</sup> *Ibid*, paras. 119-128

<sup>189</sup> Chapter 9, *Pandemic and Beyond: Building Resilience in Health Sector, XVth Finance Commission, Report for 2021-2026, October 2020* pg. 269

<sup>190</sup> Chapter 8, *Disaster Risk Management, XVth Finance Commission, Report for 2021-2026, October 2020* pg. 259

<sup>191</sup> *Reepak Kansal and Anr. v Union of India*, 2021 SCC Online SC 443

<sup>192</sup> *In re: Assessment of Criminal Justice System in Response to Sexual Offences v Union of India*, Suo Moto WP (CrI.) No. 4/2019, interim order dated 18.12.2019

<sup>193</sup> *Jan Swasthya Abhiyan & Ors. v Union of India*, WP(C) No. 289/2021, interim order dt. 27.07.2021

<sup>194</sup> *Sachin Jain v Union of India*, WP(C) No. 863/2020, interim order dt. 31.08.2020

<sup>195</sup> *Perala Shekhar Rao v Union of India*, WP (C) 898/2020, interim order dt. 11.09.2020

Among cases that have been decided, the section below highlights decisions identified relating to issues of the Bhopal gas leak disaster, the population control and family planning programme, rare diseases, COVID-19, and medical education, which are instructive of central-state government coordination and legal responsibility in relation to health as decided by the judiciary.

### 3.1.2.1 Bhopal Gas Leak Disaster

A series of orders in various petitions in the Bhopal Gas Leak Disaster case throw light on the matter of centre-state responsibility in health.

The Central Government enacted the *Bhopal Gas Leak Disaster (Processing of Claims) Act, 1985* (BGLD) in order to represent survivors of the disaster and seek compensation for harm to life, health and property. The law authorized a court-assisted settlement to provide relief to survivors and settle the liability of Union Carbide Corporation. As a group of survivors demanded direct access to justice and seek relief, for which the law provided limited opportunity, the constitutional validity of the law came to be challenged on the ground of violation of the fundamental right to access to justice. The Supreme Court upheld the central government's authority in the matter on primarily two grounds.<sup>196</sup>

First, the court invoked the doctrine of *parens patriae*, to declare that the central government has the inherent authority as the *sovereign* to provide protection to the person and property of its people, owing to its power of guardianship over its people under disability. The court added that the values of social, economic and political justice enshrined in the Preamble to the Constitution, read together with the DPSP under Article 38, Article 39<sup>197</sup> and Article 39A<sup>198</sup> enjoin the central government to secure for its people the realization of fundamental rights.

Second, the court declared that Parliament was competent to enact law on the basis of Article 253 read with Entry 13 (Participation at international conferences, bodies and implementing decisions) of List I and Entry 8 (Actionable wrongs) of List III of Schedule VII,<sup>199</sup> as the central government attempted to seek judicial remedies and compensation for survivors in the American jurisdiction in pursuance of the law, before settling the matter under domestic jurisdiction.

Having upheld the authority of the central government, the court monitored its utilization of the settlement amount for development-cum-management of the Bhopal Memorial Hospital and Research Centre (BMHRC) to provide healthcare goods, services and facilities for survivors<sup>200</sup> and establishment of

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<sup>196</sup> *Charan Lal Sahu v Union of India* (1990) 1 SCC 613

<sup>197</sup> Article 39: The State shall, in particular, direct its policy towards securing—

(a) that the citizens, men and women equally, have the right to an adequate means of livelihood;

(b) that the ownership and control of the material resources of the community are so distributed as best to subserve the common good;

(c) that the operation of the economic system does not result in the concentration of wealth and means of production to the common detriment;

(d) that there is equal pay for equal work for both men and women;

(e) that the health and strength of workers, men and women, and the tender age of children are not abused and that citizens are not forced by economic necessity to enter avocations unsuited to their age or strength;

(f) that children are given opportunities and facilities to develop in a healthy manner and in conditions of freedom and dignity and that childhood and youth are protected against exploitation and against moral and material abandonment.

<sup>198</sup> Article 39A: Equal justice and free legal aid – The State shall secure that the operation of the legal system promotes justice, on a basis of equal opportunity, and shall, in particular, provide free legal aid, by suitable legislation or schemes or in any other way, to ensure that opportunities for securing justice are not denied to any citizen by reason of economic or other disabilities.

<sup>199</sup> *Charan Lal Sahu v Union of India* (1990) 1 SCC 613

<sup>200</sup> *Union Carbide Corporation Ltd. v Union of India* 1995 Supp (4) SCC 59; *Union Carbide Corporation v Union of India* (2012) 8 SCC 362

the National Institute of Research in Environmental Health (NIREH) to study epidemiological data on morbidity and mortality caused by the gas leak to advise on care and treatment protocols.<sup>201</sup>

The Madhya Pradesh government formulated rehabilitation schemes which provided medicines through 6 hospitals and 24 dispensaries. The financial outlays for implementation of the scheme were shared by the Madhya Pradesh government and central government in the ratio of 25:75, presumably based on Finance Commission recommendations for financial allocation between state and central governments.<sup>202</sup>

Notwithstanding the validity of the BGLD Act, survivors were not divested of the right to seek remedies under writ jurisdiction to protect Article 21 rights.<sup>203</sup> When the affected parties approached the Supreme Court for monitoring accountability of the government of Madhya Pradesh in providing healthcare goods, services and facilities, the court found the government faced challenges in completing the construction of 2 hospitals and recruiting doctors due to lack of financial resources. The court directed the Chief Secretary, Madhya Pradesh to allocate the deficit amount for the same, observing:

*“It is of no concern of this court to decide as to wherefrom this money is to come from, how much is to be shared by the State Govt. or by the Govt. of India. Those are the niceties which are to be worked out by the State Govt. and the Union of India between themselves. As far as this court is concerned, health is a state subject and it is the primary duty of the State of Madhya Pradesh to provide adequate medical facilities to the gas victims. It is for this reason we are compelled to pass these orders and issue necessary directions.”<sup>204</sup>*

On this basis, the court monitored the state government’s duty in constituting oversight committees which ensured availability of medicines and clinical infrastructure, trained medical personnel and implementation of standard treatment protocols at the hospitals and clinics.<sup>205</sup>

The court also affixed joint responsibility on central and the Madhya Pradesh governments to render financial, logistical and other support to NIREH, disposal of the toxic waste and issuance of standard treatment protocols by the state committees, NIREH and BMHRC.<sup>206</sup>

### **3.1.2.2 Population Control and Family Planning Programme**

Between 2012-2016, multiple states reported serious lapses in guidelines with respect to sterilization procedures under the family planning programme, resulting in post-operative complications and deaths of women. A petition was filed before the Supreme Court to seek nation-wide accountability of ‘sterilization camps’ in compliance with central government guidelines.<sup>207</sup>

The central government stated that as public health is a state subject per Entry 6, List II of Schedule VII, it can only play a supportive and facilitative role in implementation of health-related programmes and attempted to circumvent responsibility. It claimed to have performed its role by issuance of guidelines and submitted that state governments are best positioned to locally monitor the quality of services.

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<sup>201</sup> *Bhopal Gas Peedith Mahila Udyog Sangathan v Union of India* (2012) 8 SCC 326

<sup>202</sup> Unsettling Truths, Untold Tales: The Bhopal Gas Disaster Victims 20 Years of Courtroom Struggles for Justice, Muralidhar, S., IELRC Working Paper 2004/05, pg. 42

<sup>203</sup> Id at 201, *Bhopal Gas Peedith Mahila Udyog Sangathan* para. 1

<sup>204</sup> *Bhopal Gas Peedith Mahila Udyog Sangathan v Union of India* (2000) 9 SCC 281, para. 5

<sup>205</sup> Id at 201, *Bhopal Gas Peedith Mahila Udyog Sangathan*

<sup>206</sup> Id at 201, *Bhopal Gas Peedith Mahila Udyog Sangathan*, para. 37

<sup>207</sup> Id at 119, *Devika Biswas*

The court, disagreeing with this scheme of federalism as proposed by the central government, declared that the mere issuance of guidelines does not guarantee appropriate implementation. Apart from the power of states, the court relied on Entry 20-A, List III (population control and family planning) to allocate responsibility on the central government.<sup>208</sup>

Given that public health is classified as a state subject, the court clarified the contours of centre-state responsibility in this context by proposing acting in cooperation. While implementation of national programmes is contingent on local/regional government bodies, the central government's role was affirmed as indispensable to the successful realization of the right to (sexual and reproductive) health of beneficiaries. The court noted that the legislative-cum-administrative powers of the central and state governments in matters of health should not be treated as repugnant. Rather, the court held, "*given the structure of cooperative federalism, the Union of India cannot confine its obligation to mere enactment of a scheme without ensuring its realization and implementation.*"<sup>209</sup>

Accordingly, the court disposed of the matter by issuing substantive directions to both central and state governments to monitor the implementation of guidelines on sterilization procedures.

### 3.1.2.3 Rare Diseases

Rare diseases are debilitating life-long diseases or disorders that typically affect a relatively small number of people.<sup>210</sup> Many countries have different parameters to define and respond to rare diseases based on local contexts like population disease prevalence, healthcare systems and availability of resources.

The pharmaceutical sector typically does not invest resources in research and development of medicines for rare diseases on the pretext that there is no reasonable expectation that costs of developing medicines would be recovered from sales, as rare diseases affect a minor proportion of the population. When these treatments are developed, despite receiving considerable public financing and public contributions in the development of these treatments as well as tax breaks and other incentives, the available range of medicines and treatments are priced exorbitantly. The exorbitant pricing of rare disease treatments is a global concern and like other countries, patients, families, the government and courts have grappled with this issue in India.<sup>211</sup>

In three consecutive batches of petitions before the Delhi High Court, judicial intervention has played a key role in developing a policy framework for access to treatment and medicines for rare diseases in India, by roping in central and state governments.

In the first case, *Mohd. Ahmed (minor) v Union of India*,<sup>212</sup> a child suffering from Gaucher disease approached the Delhi High Court (through the father who was a rickshaw-puller), seeking free medical treatment which cost of approximately INR 6 lakhs per month. As there was no governing medico-legal framework on treatment for rare diseases in India, the court decided to direct officials of central and NCT of Delhi governments to hold a meeting and resolve the matter amicably.<sup>213</sup>

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<sup>208</sup> Id at 119, *Devika Biswas*

<sup>209</sup> Ibid, paras. 97-98, 106-112

<sup>210</sup> Ministry of Health and Family Welfare. (2021). National Policy for Rare Diseases, 2021. Available at: <https://main.mohfw.gov.in/sites/default/files/Final%20NPRD%2C%202021.pdf>

<sup>211</sup> Luzzatto, L., et al (2015), Rare diseases and effective treatments: are we delivering? *The Lancet*, Vol. 385, Issue 9970, pgs. 750-752

<sup>212</sup> (2014) 6 HCC (Del) 118

<sup>213</sup> Id at 60, *Mohd. Ahmed (minor)*

As the respective governments failed to arrive at a solution, the court decided to adjudicate the matter on the basis of India's commitment to realize the right to the highest attainable standard of physical and mental health under Article 21 read with DPSPs, which includes access to life-saving drugs as a non-derogable right. In particular, the court noted that General Comment 14 to ICESCR's norm of *the obligation to fulfil*, which requires India to recognize the right to health in national political and legal systems.<sup>214</sup>

In terms of immediate relief, the court directed the Delhi government to provide treatment at a super-specialty hospital free of charge, on the ground that public health is a state subject.<sup>215</sup> Notably, the court issued directions to both the central and Delhi governments to constitute a joint committee to consider developing a policy for rare diseases and promoting research and development of medicines for the same.<sup>216</sup>

As seen in the subsequent cases, this particular direction to the central and state governments to consider framing a policy on the basis of Article 21 read with the obligation to fulfil under ICESCR assumed binding force on evolving a legal policy framework for rare diseases in India.

In the second case, *Baby Devananda D. (through mother) v Employees State Insurance Corporation*,<sup>217</sup> a group of children suffering from Gaucher Type I and Hurler Syndrome Type I diseases approached the Delhi High Court through their parents, seeking application of the Employee State Insurance Corporation (ESIC) guidelines for providing treatment at empanelled super-specialty hospitals as their parents/government employees were covered by ESIC.<sup>218</sup>

Here, the court started monitoring the implementation of its order on the framing of policy issued in the previous case. As no developments were reported on the policy front, the court directed the MOHFW, Ministry of Labour, Ministry of Corporate Affairs and the ESIC to convene a meeting for the same. In response, government representatives undertook the framing of a policy for rare diseases. Subsequently, the MOHFW submitted before court that the *National Policy for Treatment of Rare Diseases, 2017* was formulated for patients not protected under existing financial coverage health schemes by government.<sup>219</sup>

However, this initial policy faced resistance from the governments of Kerala, Delhi and Tamil Nadu for primarily assigning financial responsibility for treatment of rare diseases on states, and was ultimately withdrawn by MOHFW with an explicit undertaking that a fresh policy will be framed in nine months in consultation with states in accordance with the court's order in *Mohd. Ahmed*.<sup>220</sup>

Since the policy-making process continued parallel to the proceedings, the court resumed its attention to granting relief in the immediate matter before it, i.e., access to treatment for the petitioners. As the ESIC attempted to avoid financial liability for the super-specialty treatments by claiming that public health is a state subject and therefore the Delhi government should bear such expenses, the court assigned responsibility to the public sector corporation by force of Entry 47 (Insurance), List I, Entry 23 (Social security and social insurance; employment and unemployment), List III and Entry 24 (Welfare of labour including conditions of work, provident fund, employer's liability, workmen's compensation, invalidity and old age pensions and maternity benefits), List III of Schedule VII.<sup>221</sup>

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<sup>214</sup> Ibid, paras 49-58, 68

<sup>215</sup> Ibid, para. 89

<sup>216</sup> Ibid, para. 81

<sup>217</sup> 2017 SCC Online Del 12779

<sup>218</sup> *Baby Devananda D. (through mother) v Employees State Insurance Corporation* 2017 SCC Online Del 12779

<sup>219</sup> Ibid, paras. 34-36

<sup>220</sup> Ibid, paras. 42-45

<sup>221</sup> Ibid, paras. 54-55

The court also dismissed ESIC's contention that it should not be held liable for providing super-specialty treatments which incur high costs, by declaring that the ESIC was a statutory body under a social welfare law – the *Employee's State Insurance Act, 1948* – therefore it was impermissible to discriminate between provision of ordinary healthcare services vis-à-vis super-specialty healthcare services. The court disposed of the matter by directing the ESIC or its empanelled hospitals to provide treatment for rare diseases of the petitioners and bear cost of the same.<sup>222</sup>

In the third case, *Master Arnesh Shaw v Union of India*,<sup>223</sup> a group of children suffering from Duchenne Muscular Dystrophy approached the Delhi High Court (through their parents) to seek access to treatment. As the MOHFW's *Draft Health Policy for Rare Diseases, 2020* was still under deliberation, the court directed the ministry to specify a fixed timeline for notifying the same.<sup>224</sup>

Similar to *Baby Devananda*, the court balanced interests of the petitioners/patients for access to treatment and notification of the policy concurrently.<sup>225</sup> In consultation with central government representatives and private healthcare providers, the court recommended that the national policy respond to concerns of local development of affordable drugs, state-level constitution of Centres of Excellence (COE) under leadership of AIIMS, New Delhi for prevention and treatment of rare diseases, a fund to be established by MOHFW for treatment of patients and building a digital crowd-funding platform to be linked to the MOHFW fund.<sup>226</sup>

Eventually, the MOHFW notified the *National Policy for Rare Diseases, 2021* consistent with the court's orders. The Delhi High Court is continuing to monitor the implementation of the policy and has clubbed the *Master Arnesh* case with multiple other petitions, including 39 petitions each of which has been filed for a child with a rare disease and facing significant barriers to accessing treatment. Noting various gaps in the implementation of the policy and the urgent treatment needs of many of the petitioners, the court has now constituted a high-level National Rare Diseases' Committee comprising two professors from AIIMS, the Secretary, MOHFW, the Director of ICMR and the DCGI. The mandate of the committee as laid down by the Court is:

*"21. The mandate of the Committee would broadly be to take all steps needed for implementation of the National Rare Disease Policy, 2021. The mandate of the Committee shall include:*

*(i) Procurement of therapies & drugs and creation of associated logistical framework for administration of treatment for patients with rare diseases;*

*(ii) Recommending necessary steps for the indigenisation of therapies, medicines for rare diseases and identify the manner in which the same can be made accessible to the lakhs of patients who, as per the Policy, are suffering from rare diseases;*

*(iii) The Committee, while working broadly under the umbrella of the Policy, would undertake a periodic review of the Policy and recommend to the Ministry of Health and Family Welfare, the changes needed in the Policy if the same is deemed necessary.*

*22. In addition to the above mandate, the immediate requirement of the patients whose treatment has been stopped due to lack of funding, and whose details have been captured in paragraph 16 of the order dated 3rd May, 2023 shall be taken up by the Committee on an urgent basis, so that the treatment can be re-commenced. The Committee would be free to contact the providers or manufacturers or distributors of the DMD therapies as also*

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<sup>222</sup> Ibid, paras. 58-59, 80

<sup>223</sup> WP (C) No. 5315/2020

<sup>224</sup> Id at 91, *Master Arnesh Shaw* order dt. 12.01.2021

<sup>225</sup> Ibid, order dt. 02.03.2021

<sup>226</sup> Ibid, order dt. 23.03.2021



*other therapies, in a manner to ensure immediate commencement of providing adequate doses for the said patients.*

*23. The Committee is also free to consult any other persons or organisations as Invitees to the Committee meetings to work for the overall objective of the Policy. The Committee may also contact any subject expert or persons with domain knowledge for the sake of expediting the procurement of medicines or therapies. For the said purpose, if any contact details of the patients or the providers of therapies are required, Id. Counsel for the Petitioners, AIIMS or the Id. standing counsel is free to provide the same to the Committee.*<sup>227</sup>

#### **3.1.2.4 COVID-19**

As discussed in Section 2, the Supreme Court recommended that the central government amend its liberalized COVID-19 vaccine policy to centrally procure vaccines and distribute to state governments for better administration, in the interest of equitable access to vaccines for all under Article 14 and Article 21. In the context of limited financial resources available with state governments, the court noted that compelling them to compete with private hospitals and directly procure vaccines would impede access as state governments held the discretion to administer vaccines for free or subsidized rates. The additional expenditure to be borne by state governments for procuring vaccines would also impact availability of funds for scaling-up general health infrastructure as per local needs.<sup>228</sup>

Although public health is a state subject, the court accepted *amicus curiae* submissions on allocating responsibility on the central government to play a more active role with state governments based on Entry 81 (inter-State migration and inter-State quarantine), List I and Entry 29 (Prevention of extension from one State to another of infectious or contagious diseases or pests affecting men, animals or plants), List III of Schedule VII. Therefore, pandemic management and control, and vaccination policy and pricing, were declared the responsibility of the central government, which had to work in tandem with state/UT governments. The liberalized COVID-19 vaccine policy, by putting the financial burden of vaccination of persons in the 18-44 years group on the states/UTs, conflicted with this constitutional balance of responsibilities between the centre and states/UTs.<sup>229</sup>

The court relied on the scheme of the DMA to note that this law was enacted in a spirit of cooperative federalism. Thus, the central government must assist state governments in effectively tackling the pandemic, including in broader aspects of medical infrastructure.<sup>230</sup>

The critical supply of medical oxygen during the second wave of COVID-19 also involved complex negotiations between central and state governments. The Delhi High Court and the Supreme Court held simultaneous hearings to direct the central government to monitor the financial and logistical barriers in supply of medical oxygen in NCT of Delhi and throughout India. The courts invoked Entry 42 (Inter-state trade and commerce), List I and Entry 20 (Economic and social planning), List III of Schedule VII by directing the MOHFW and Department for Promotion of Industries and Internal Trade to meet and deliberate on the diversion of oxygen from industrial use to medical supply and further directed the central government to issue appropriate orders to the steel and petrochemical industries for the same.<sup>231</sup>

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<sup>227</sup> *Master Arnesh Shaw v Union of India*, WP (C) No. 5315/2020 & connected matters, order dt. 15.05.2023

<sup>228</sup> Id at 92, *In re: Distribution of essential supplies and services during pandemic* order dt. 30.04.2021, paras. 43-44 and order dt. 31.05.2021, para. 33

<sup>229</sup> Ibid, order dt. 31.05.2021, para. 9.8

<sup>230</sup> Id at 92, *In re: Distribution of essential supplies and services during pandemic* order dt. 30.04.2021, paras. 7, 15

<sup>231</sup> *Rakesh Malhotra v GNCTD*, WP(C) No. 3031/2020, order dt. 20.04.2021, paras. 11-14 read with order dt. 01.05.2021, para. 2 and *Union of India v Rakesh Malhotra*, SLP No. 11622/2021, order dt. 05.05.2021

In response, the Home Ministry issued orders under the DMA to ensure free and uninterrupted inter-state movement and supply of medical oxygen by manufacturers, distributors and others. The central government also constituted an Empowered Group for coordinating medical logistics, review demands for medical supply of oxygen and prepared a plan in consultation with state/UT governments.<sup>232</sup> The court took note of the developments and directed all state/UT governments to coordinate directly with the central government for supply/demand concerns of medical oxygen henceforth.<sup>233</sup>

During this process, the court noted that disputes relating to allocation of financial resources by central or state governments must not frustrate the government's attempts at facilitating access to essential medical services and should be worked out at a later stage.<sup>234</sup>

### 3.1.2.5 Medical Education

Lastly, this section deals with an area of much debate and judicial consideration relating to the powers of central and state governments in reservation of seats for in-service candidates in medical post-graduate (PG) degree courses and super-specialty courses to augment human resources for rural and remote areas.

An important area of contention between central and state governments' legislative competence has arisen in the area of medical education – a shared area between the centre (Entry 66 List I)<sup>235</sup> and states (Entry 25 List III).<sup>236</sup> The subject of "education" was moved from List II (State List) to List III (Concurrent list) by the 42<sup>nd</sup> *Constitutional Amendment Act*.<sup>237</sup> This was done, among other reasons, so that Parliament could secure uniformity in standard and syllabi of education in the country.

By virtue of Entry 66 List I, Parliament passed the *Indian Medical Council Act, 1956* (MCI) to regulate standards of medical education, permission to start colleges, permission to start courses or increase the number of seats, registration of doctors and standards of professional conduct of medical practitioners.

Regulation 9 of the *Medical Council of India Postgraduate Medical Education Regulations 2000 (MCI PG Regulations)* (amended in 2012 and operative from year 2013-14), states that admission to PG courses shall be based on merit through the single eligibility-cum-entrance examination, namely, 'National Eligibility-cum-Entrance Test' (NEET). However, in the public interest to improve availability of doctors in rural, remote and difficult-to-access areas, Regulation 9, Clause (IV) provides that determination of merit may include incentives for both diploma and degree PG courses (weightage in marks to be added to the marks obtained by them in NEET)<sup>238</sup> and Clause (VII) provides for reservation of seats for in-service doctors for services rendered in rural and remote areas only for diploma PG courses and not for degree courses.

Several states passed specific laws or government orders providing for reservation for in-service doctors, who have served for a certain number of years in government PHCs, CHCs in rural areas, even in PG degree courses with the objective of correcting the shortfall of doctors in rural areas. These provisions have been

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<sup>232</sup> Ibid, order dt. 22.04.2021, para. 5

<sup>233</sup> Id at 231, *Rakesh Malhotra* order dt. 26.04.2021, para 10.

<sup>234</sup> Id at 231, *Rakesh Malhotra* order dt. 01.05.2021, paras. 4-7

<sup>235</sup> Covers coordination and determination of standards in institutions for higher education and scientific and technical institutions.

<sup>236</sup> Covers education including medical education and universities, subject to the provisions of entries 63 – 66 of List I.

<sup>237</sup> The 42<sup>nd</sup> *Amendment Act* of 1976 transferred five subjects to Concurrent List from State List, that is, (a) education, (b) forests, (c) weights and measures, (d) protection of wild animals and birds, and (e) administration of justice; constitution and organisation of all courts except the Supreme Court and the high courts.

<sup>238</sup> The proviso to Regulation 9 Clause (IV) states that in determining the merit of candidates who are in-service of Government/public authority, weightage in marks may be given as an incentive at the rate of 10% of the marks obtained for each year of service in remote and/or difficult areas up to the maximum of 30% of the marks obtained in NEET. This would be applicable to degree courses as well as diploma courses.

challenged as being *ultra vires*, i.e., violating the former MCI Act, which did not provide for reservations of seats for degree courses. In several states, a practice has been followed that for about 100 seats in the pool of eligible candidates, 50 are attributed to the All-India category and 50 to the state quota. Of the latter, 25 seats are allocated open seats and 25 are reserved for in-service candidates.<sup>239</sup> The section below reviews key centre-state developments and the judicial response on evolving a federated system on medical education.

### Uttar Pradesh

The state of Uttar Pradesh (UP), by way of a Government Order in 2014, created reservation of 30 percent for in-service candidates for admission to post-graduate medical courses in six state medical colleges. Such reservation could be availed by those persons who had passed the common entrance examination, if they had served in health centres or PHCs or CHCs in difficult, remote and backward areas, for a period of three years or more. The UP Government Order was challenged by in-service candidates in urban areas before the Allahabad High Court as violative of Regulation 9 of the *MCI PG Regulations*.

The High Court struck down the Government Order on the basis that the *MCI PG Regulations*, being a complete binding code in itself, did not provide for any reservation for admission to PG degree courses.<sup>240</sup> In appeal to the Supreme Court, the state government argued that the *MCI PG Regulations* did not explicitly bar states from providing reservation for in-service candidates in the 'degree' courses and that there were precedents suggesting that such arrangement is permissible as a separate channel of admission for in-service candidates. However, the Supreme Court agreed with the High Court and declared that the UP Government Order was contrary to Regulation 9 of the *MCI PG Regulations*.<sup>241</sup>

### Tamil Nadu

The state of Tamil Nadu has since 1989, provided a separate source of entry to in-service candidates in up to 50 percent of the seats in degree courses. From 2007 onwards the state has given preference in weightage to in-service candidates who have worked in remote, hilly, and challenging areas.

Pursuant to the Supreme Court's declaration on the UP Government Order, the Tamil Nadu Medical Officers' Association (TNMOA) and others filed a writ petition before the Supreme Court, seeking the following declarations: (a) that Regulation 9 of the *MCI PG Regulations*, do not negate the competence of the States under Entry 25, List III of concurrent List, to devise a separate entry for in-service candidates to be admitted to Degree Courses; and (b) alternatively, that Regulations 9(iv) and 9 (vii)] are struck down as arbitrary, discriminatory and falling foul of Article 14 and Article 19(1)(g) of the Constitution, as well as *ultra vires* the provisions of the *MCI PG Regulations*.

Similar reliefs were sought on behalf of in-service doctors in Kerala, Maharashtra, Haryana and West Bengal. These matters were clubbed together as they implicated a common question of law and referred to a five-judge constitutional bench of the Supreme Court.

The following contentions of the in-service candidates are instructive to understand the role of reservations as a policy measure in facilitating availability of medical professionals for rural healthcare:

- i. State governments' measures for in-service quota is in keeping with its constitutional obligation under Article 47, to provide better healthcare facilities to its citizens by upgrading the skills and

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<sup>239</sup> Jain, M., (2018), Livelaw.in, *Can States Provide Reservation For In-Service Candidates For PG Medical Courses? SC Constitution Bench Reserves Interim Order*; available at: <https://www.livelaw.in/can-states-provide-reservation-service-candidates-pg-medical-courses-sc-constitution-bench-reserves-interim-order/>

<sup>240</sup> *Dr. Dinesh Singh Chauhan v State of Uttar Pradesh & Ors.*, WA No.34118/2015, order dt. 07.04.2016

<sup>241</sup> *State of Uttar Pradesh & Ors. v Dinesh Singh Chauhan* (2016) 9 SCC 749

- qualifications of the existing in-service doctors. This measure is also necessary to fulfil the fundamental right to health of the citizens protected under Article 21.
- ii. If Regulation 9 is interpreted in a manner that prohibits a distinct source of entry for in-service candidates in degree courses, it would be wholly arbitrary, as it would completely fail to take into account the problems posed to delivery of health services, due to shortage of medical staff at both basic and specialised levels in rural areas.
  - iii. The issue does not entail a conflict between the legislative fields of the centre and the states. The field of Central Legislation is related to laying down minimum standards of medical education and the state legislation has provided for in-service quota without impinging on the prescribed minimum standards under the central legislation.

In a significant decision, the Supreme Court in *Tamil Nadu Medical Officers' Association & Ors. (TNMAO) v UOI & Ors.*<sup>242</sup> authoritatively declared that state governments are empowered to provide a separate channel/source of entry by reservation for admission to PG degree/diploma medical courses insofar as in-service candidates are concerned by virtue of List III Entry 25.<sup>243</sup> As it overruled its previous decision on the UP Government Order,<sup>244</sup> the court held that MCI laws and regulations under authority of Entry 66, List I have no power on reservations. Therefore, the impugned Regulation 9 of the *MCI PG Regulations* to the extent it interferes with reservation provided by the states for in-service candidates was held to be unconstitutional as being arbitrary, discriminatory and violative of Articles 14 and Article 21.

Additionally, the court held that state governments cannot be held to have encroached on the central government's powers to determine standards of education under Entry 66, List I as the state's legislative powers in granting reservation is derived from concurrent powers under Entry 25, List III to reshape education policy in order to adequately provide healthcare personnel in rural areas in fulfilment of its constitutional duties. The court observed that the reservation for in-service doctors has been a long-standing practice and states are instituting such measures to achieve the laudable purpose of making available improved access to healthcare delivery in rural areas.

#### Reservation for in-service candidates in super-specialty medical degree courses

In *TNMOA*, the Supreme Court settled the legislative competence of states to provide reservation for in-service candidates in PG degree courses. The question of whether the same was permitted for super-specialty courses came up subsequently before the court in a different matter. By a government order (G.O.) of November 2020, Tamil Nadu provided 50 percent reservation in seats for in-service doctors in super-specialty courses for the admission year 2020-21. On petitions filed before it, the Supreme Court granted an interim stay on the G.O. for the academic year 2020-21, primarily because it was issued after the admission process had begun. It did not, however, pass any order on the legal validity of the G.O.<sup>245</sup>

However, after the judgment in *TNMOA*, Tamil Nadu re-issued a similar G.O. for academic year 2021-22, but this time before the commencement of the admission process. A writ petition was filed seeking that the earlier interim stay be continued for academic year 2021-22 as well. The Supreme Court took note of the fact the new G.O. for 2021-22 was issued prior to the commencement of the admission process and that the earlier interim order was not passed on the legal validity of the G.O. The court took further note of the decision in *TNMOA* and vacated the interim stay, thereby permitting the Tamil Nadu government

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<sup>242</sup> (2021) 6 SCC 568, para. 20

<sup>243</sup> *Tamil Nadu Medical Officers' Association & Ors. v UOI & Ors.* (2021) 6 SCC 568, para. 20

<sup>244</sup> Id at 240, *Dr. Dinesh Dingh Chauhan*

<sup>245</sup> *Dr. Prerit Sharma & Ors. v Dr. Bilu BS & Ors.*, WP No. 1299/2020, interim order dt. 27.11.2020, directing that counselling for admission to super specialty medical courses for the academic year 2020-2021 shall proceed without providing for reservation to in-service candidates/doctors.

to continue with the 2021-22 G.O. and allocate 50 percent super-specialty seats in government medical colleges to NEET-qualified in-service candidates.<sup>246</sup>

### Assam and Chhattisgarh

The state of Assam passed the *Assam Rural Health Regulatory Authority Act, 2004* (ARHRA Act) to create a cadre of rural health practitioners (RHPs) to respond to the chronic shortage of trained human resources for healthcare in rural areas of the state. The law granted powers to the government to establish a medical institution and introduce a 3.5 years Diploma in Medicine and Rural Health Care (DMRHC). From 2009-2013, health sub-centres (HSCs) are credited as better performing due to the role of RHPs in management of out-patient department (OPD) services like diagnosis, referral and treatment for minor ailments, communicable diseases, non-communicable diseases, emergency cases and remarkable improvement in reproductive and child health services, which resulted in a gradual decline in overall mortality rates in a majority of high-risk districts of Assam.<sup>247</sup>

Despite this successful effort by the Assam government, the Gauhati High Court declared the complete scheme of the ARHRA Act as unconstitutional on challenge by the state chapter of the Indian Medical Association (IMA) in 2014.<sup>248</sup> The main ground of challenge by IMA was that the state-level ARHRA Act which was enacted on the basis of Entry 25, List III (Concurrent) of Schedule VII of Constitution, conflicted with the national level *MCI Act, 1956* which was enacted on basis of Entry 66, List I (Union) of Schedule VII of the Constitution and was therefore unconstitutional for usurping powers of the Central Government.

In a decision that ignored the evidence of RHPs successes in improvement in rural health indicators on the ground, the court accepted IMA's submissions and declared that the Assam RHPs would ostensibly be inadequately trained as they do not conform to IMC norms, thus, striking down the entire law and effort by the Assam Government in taking special measures to respond to rural health concerns. The Assam government subsequently passed the *Assam Community Health Professionals (Registration and Competency) Act, 2015* (ACHP) in order to regularize the qualifications and working conditions of the former RHPs and absorbed them at the HSC levels as paramedical personnel to assist medical officers.

The State of Chhattisgarh also faced similar resistance by the IMA when a community health worker programme was introduced in 2001 (*Chhattisgarh Chikitsa Mandal*). Community health workers were intended to serve as a bridge between large number of underserved populations in rural and backward areas which reported very low on availability of trained medical practitioners. However, IMA submitted that the programme would end up replacing doctors and lower the standard of healthcare delivery. Without explicitly pronouncing on the legal validity of the state government's effort, the High Court oversaw the government discontinue the programme in 2008 and modify terms of service conditions of graduates to prevent any conflict with MCI standards. In 2020, the trained personnel were renamed as Rural Medical Assistants (RMA), as they are authorized to perform limited medical procedures only under direct supervision of medical practitioners.<sup>249</sup>

As noted for Assam, the RMAs in Chhattisgarh are reported to have a notably positive impact on service delivery at the PHC-level and found to be equally competent as medical practitioners. Notwithstanding the legal disputes on the states' rural medical education programmes, Assam and Chhattisgarh's efforts

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<sup>246</sup> *Dr. N. Karthikeyan v State of Tamil Nadu* 2022 SCC Online SC 331

<sup>247</sup> Meeting the Primary Healthcare needs of Assam through introduction of a Mid-Level Health Worker: Lessons from India's experience with Rural Health Practitioners, Lisam, S., Indian Journal of Forensic and Community Medicine, Jan-Mar 2015

<sup>248</sup> *Indian Medical Association (Assam State branch) v State of Assam*, WP(C) No. 5789/2005 disposed of by order dt. 30.10.2014

<sup>249</sup> *Indian Medical Association v State of Chhattisgarh*, 2020 SCC Online Chh 1518

in augmenting trained healthcare workers for rural and backward areas are viewed as historical landmarks within policy circles and formed the basis for recommendations on sanctioning a Bachelor in Rural Medicine and Surgery (BRMS) course in order to realize the goal of universal health care.<sup>250</sup>

The Delhi High Court is currently monitoring the central government's decision-making process on implementation of a short-term course (B.Sc., Community Health) in consultation with the MCI, to train health workers to deliver primary healthcare in rural areas and license the practitioners graduating from the programme, as recommended by a Task Force on Medical Education by the NRHM. Even though a policy decision on introducing the course was taken in 2010,<sup>251</sup> the government has not implemented the programme and is awaiting the outcome of a batch of appeals on the Assam effort<sup>252</sup> for legal certainty on the validity of its medical course for rural healthcare.<sup>253</sup>

As *TNMOA* governs the field on laying the framework on complementary responsibilities of centre and states on medical education, state governments' efforts at augmenting trained healthcare workers for rural and backward areas, whether by reservations or introducing special courses, must receive the autonomy and support they deserve from courts, apex medical associations and the centre in promoting public health for underserved areas.

### **3.1.3 Propositions of law emerging from key decisions on cooperative federalism and health**

A review of the cases discussed above clarifies that the mere classification of 'public health, hospitals, dispensaries' as a state subject under List II of the Constitution does not absolve the central government of its responsibility on health. In fact, this classification in practice only mandates state governments to make infrastructure related to public health goods, services, and facilities available at a regional level. The central government is implicated in governance in health –including planning, making financial allocation, providing technical stewardship and support to build capacities of state governments and monitoring implementation. As noted by the courts, this must be achieved in the spirit of cooperative federalism with the states. Indeed, these responsibilities emerge foundationally from Article 21 and India's treaty obligations under the ICESCR as reified by General Comment 14 and a complementary reading of the distribution of powers between the centre and states.

The judiciary has found that the central government is accountable for ensuring right to health and promoting public health in cooperation with state governments on the following grounds:

- i. The doctrine of *parens patriae* mandates that the central government has the inherent authority as the *sovereign* to provide protection to the person and property of its people.
- ii. The values of social, economic and political justice enshrined in the Preamble to the Constitution, read together with Articles 38, 39, 39A and 47 (DPSPs) enjoin the central government to secure for its people the realization of fundamental rights.
- iii. By virtue of Entries 13 and 14 of List 1 (Union) of Schedule VII, it is the central government that has the power to enter into and implement treaties and conventions, such as the ICESCR. Article 253 of

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<sup>250</sup> Summary Report of NHSRC Studies on Strategies for Improving Availability of Healthcare Providers in Rural and Remote Areas (2013), available at: <https://nhsrcindia.org/sites/default/files/2021-06/Summary%20Report%20of%20NHSRC%20Studies%20on%20Strategies%20for%20Improving%20Availability%20of%20Healthcare%20Providers%20in%20Rural%20Remote%20Areas.pdf>

<sup>251</sup> *Meenakshi Gautham v Union of India*, WP (C) No. 13208/2009, order dt. 10.11.2010; *Meenakshi Gautham v Union of India*, 2015 SCC Online Del 11696

<sup>252</sup> *Baharul Islam v Indian Medical Association*, SLP No. 032592-032593/2015

<sup>253</sup> Id at 251, *Meenakshi Gautham* order dt. 16.11.2022

the Constitution empowers Parliament to pass legislations to implement obligations arising from such conventions, even if it otherwise encroaches on subject matters in the State list. The central government has passed several laws concerning public health under Article 253 (mental health, HIV and AIDS, disability). The legislative domain is coterminous with the executive and administrative scope of action including issuing policies, programmes and schemes.

- iv. Several aspects of health are in various entries contained in List I (Union) and List III (Concurrent) of Schedule VII. For instance, those concerning mental health, infectious disease control, population control and family planning, insurance, social security and economic planning, among others. The courts have read these entries to hold the centre responsible for undertaking budgetary, policy and programmatic measures along with the states to shoulder joint responsibility for health.
- v. The central government has health administration setup at the central level (MOHFW) and runs national health programmes and schemes with the states to promote public health. The duty to promote public health mandates the central government to actively monitor the implementation of such programmes or schemes and provide support to states for the same.
- vi. Lastly, Article 21 and India's treaty obligations under the ICESCR mandate the central government to respect, protect and fulfil the right to health.

With respect to cost-sharing between centre and states for health-related matters, courts have responded in largely two ways – they may direct that sufficient funds should be made available for relief or services, or simply pass substantive orders for provision of services without passing orders related to funds or cost-sharing. In either case, courts seldom get into specifics of cost-sharing between the centre and state. Instead, this issue is usually reserved for the executive domain to be resolved cooperatively between the central and state governments, presumably on the basis of existing financial norms of allocation of resources.

## **3.2 Regulation of the private health sector**

As the Indian government moves from a provider to a regulatory role due to increased participation of the private sector in health delivery, the regulation of the private sector becomes a vital function of the government. Various regulatory and judicial forums have stepped in to regulate the private healthcare sector and provide relief to the public. The issues they deal with range from exclusionary and arbitrary terms by insurance service providers and obligations of healthcare establishments to patients, to medical professionals' duty of care and the pricing policy of pharmaceutical drugs. The following section provides an overview of the legal policy concerns arising in this context, vital as they are not just to understand how a largely unregulated sector is brought within the ambit of the right to health, but also to suggest their relevance to a UHC vision that involves the private sector. In the first part, we review judicial interventions in terms of the nature of redress available to aggrieved parties under existing statutory law in various contexts. In the second part, we review how courts have innovated accountability measures for the private sector where statutory law is inadequate or non-existent, by invoking the duty to respect, protect and fulfil constitutional rights.

### **3.2.1 Courts and the legislative framework relating to the private health sector**

#### **3.2.1.1 Health insurance**

Courts have typically held that public and private health insurance providers must meet fair, just and reasonable (Article 14) standards in matters of renewal of policies or coverage of pre-existing conditions.

Insurers cannot cancel policies on ‘*high claim ratio*’ grounds as this militates against principles of public policy. The area of health insurance is qualitatively different from general insurance, therefore to withstand legal scrutiny, service providers must be cognizant of statutory law, Insurance Regulatory Development Authority (IRDA) regulations and international human rights principles.<sup>254</sup>

The denial of coverage of pre-existing conditions is a significant concern, for instance, in cases of persons with TB, who can be denied coverage or be charged a hefty premium for declaring they have TB. This often discourages self-revelation of their status, and denial of claims for this non-revelation in the future. As the Supreme Court has pointed out, public insurance companies have a ‘*public duty*’ to create terms and conditions in policies that are just and fair to ensure access to all members of society:

*“The eligibility conditions must be conformable to the Preamble, Fundamental Rights and Directive Principles of the Constitution... The rates of premium must also be reasonable and accessible. It may be made clear that the with a view to make the policy viable and easily available to the general public, it may be open to the appellants to revise the premium... but it must not be arbitrary, unjust, excessive and oppressive.”<sup>255</sup>*

In the context of the asymmetry of information between users and health insurance companies, courts have held that the latter cannot rely on contractual ‘*duty to disclose*’ conditions to deny reimbursements for treatments of high-risk health conditions associated with pre-existing conditions, if the user is not formally diagnosed with the former.<sup>256</sup> Courts have also set aside acts of insurers who unilaterally insert caps on coverage or limitations on available range of treatments, deceiving users into accepting the same on the premise of renewal of policy as per existing terms and conditions.<sup>257</sup> The rights of insured persons have been protected in such cases and service providers have been directed to pay the insured sum as well as costs of litigation.

In recent developments, courts have examined the legal validity of insurance policies on the basis of anti-discrimination law. The validity of health insurance policies which exclude coverage completely<sup>258</sup> or provide inadequate coverage<sup>259</sup> to mental health conditions like severe depression, schizophrenia, bipolar disorder and others are being examined by courts for violation of statutory obligations under section 21(4) of the MHCA, which mandates all healthcare goods, services and facilities, including health insurance to be provided for persons with mental illness on an equal basis as persons with physical health conditions. Additionally, courts have declared that Article 25 of the *Convention on the Rights of Persons with Disabilities*<sup>260</sup> guarantees the right to medical insurance for persons with mental illness on a non-discriminatory basis, underlining the application of domestic law in conformity to international human rights principles.<sup>261</sup>

Courts have observed that insurance policies subscribed prior to the coming into force of a new law (such as the MHCA) must be amended immediately to guarantee the protection of rights according to applicable law. As the case on inadequate coverage<sup>262</sup> is still sub-judice, the court has not ordered any relief yet. However, the case on complete exclusion has been finally determined, with the court decreeing the

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<sup>254</sup> *Biman Krishna Bose v United India Insurance* 2001 (6) SCC 477; *United India Insurance v Manubhai Dharmsinhbhai Gajera* 2008 (10) SCC 404

<sup>255</sup> *Life Insurance Corporation of India v Consumer Education and Research Centre* (1995) 5 SCC 482

<sup>256</sup> *Manmohan Nanda v United India Assurance Co. Ltd.*, 2021 SCC Online SC 1181

<sup>257</sup> *Jacob Punnen v United India Insurance*, (2022) 3 SCC 655

<sup>258</sup> Id at 115, *Shikha Nischal*

<sup>259</sup> *Subhash Khandelwal v Max Bupa Health Insurance Co. Ltd.*, WP(C) No. 4010/2021, order dt. 15.04.2021

<sup>260</sup> United Nations Convention on the Rights of Persons with Disabilities (2006, December 13).

<sup>261</sup> *Saurabh Shukla v. Max Bupa Health Insurance Co. Ltd. & Ors.* W.P.(C) 6074/2019, order dt. 13.12.2022

<sup>262</sup> *Subhash Khandelwal v Max Bupa Health Insurance Co. Ltd.*, WP(C) No. 4010/2021, order dt. 15.04.2021



service provider to pay the aggrieved party the full sum insured under the policy towards expenses borne for treatment of schizoaffective disorder.<sup>263</sup>

The IRDA issued a circular in 2018 to guide the insurance industry on its legal obligations in response to these litigations and has reiterated them over time.<sup>264</sup> However, courts have directed that the IRDA is mandated as per the *Insurance Development and Regulatory Authority Act, 1999* to actively monitor, supervise and ensure public and private service providers' compliance of the law.

Likewise, the Delhi High Court held that exclusion of genetic conditions from insurance coverage is unconstitutional as discrimination on basis of genetic conditions is prohibited by Article 14 and Article 21.<sup>265</sup> It observed that an individual's right to access health insurance is an inalienable component of the right to health, as without insurance, access to affordable healthcare is challenging under Indian healthcare systems.

The court added that health insurance contracts must be structured based on empirical data in order to determine differential payment of premium to service providers in context of a specific genetic condition. However, policies cannot be 'exclusionary' *per se*. On this basis, it directed the service provider to pay the full sum insured to the aggrieved party.

While the Delhi High Court's decision on genetic conditions has been currently stayed by the Supreme Court,<sup>266</sup> IRDA has already issued a circular in 2019 on standardization of exclusions in health insurance policies, which forbids exclusion of genetic conditions from coverage.<sup>267</sup>

In the area of health insurance, commercial agreements are mandated to comply with the governing field of statutory law, IRDA regulations and international human rights principles to protect the right to health under Article 21. Apart from issuing regulations to guide the business activities of service providers, the IRDA also has a positive duty to monitor, supervise and ensure compliance with extant law. The impact of IRDA regulations is underscored by the case on genetic conditions. The adherence of constitutional law standards by the public health insurance sector is an established position in law. However, the private health insurance sector is also bound to comply with constitutional principles enshrined in Article 14 and Article 21 by the instrument of IRDA regulations, which are amended to reflect evolving status of statutory and constitutional law.

### 3.2.1.2 Healthcare establishments

It is settled law that patients have legal remedies as consumers for medical malpractice, negligence or deficiency of service against hospitals, nursing homes, health centres, dispensaries, insurance providers and medical practitioners who offer healthcare services in exchange of payment in form of diagnosis, consultations or treatment (medicinal or surgical), in public and private sector, under the *Consumer Protection Act, 1986*.<sup>268</sup> This includes patients who cannot afford to pay for services at public healthcare establishments on account of social or economic backward status, as public healthcare establishments cross-subsidize poor patients through payments received from patients who can afford to pay.

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<sup>263</sup> Id at 115, *Shikha Nischal*

<sup>264</sup> Insurance Regulator and Development Authority of India (2018). *The Mental Healthcare Act, 2017*, IRDA/HLT/MISC/CIR/128/08/2018, available at: <https://irdai.gov.in/document-detail?documentId=388890>

<sup>265</sup> Id at 114, *Jai Parkash Tayal*

<sup>266</sup> *United India Insurance Ltd. v Jai Parkash Tayal*, SLP (C) Diary No. 29590/2018, order dt. 27.08.2018

<sup>267</sup> Insurance Regulator and Development Authority of India (2019). *Guidelines on Standardization of Exclusions in Health Insurance Contracts*. Ref. No: IRDAI/HLT/REG/CIR/177/09/2019, available at: <https://irdai.gov.in/hi/document-detail?documentId=392498>

<sup>268</sup> Id at 130, *VP Shantha*

After recent amendments to the consumer law, courts have restated the settled position that the *Consumer Protection Act, 2019* (CPA) applies to individuals and establishments providing healthcare related services<sup>269</sup>, in response to a petition by medical practitioners seeking exemption from accountability of medical services under the law.<sup>270</sup>

The *Clinical Establishments Act, 2010* (CEA) passed by the central government by powers accorded to it under Article 252 is currently applicable in 13 states and 6 UTs which have adopted it.<sup>271</sup> The purpose of the law is to advance the mandate of improving public health under Article 47 by providing for registration and regulation of public and private clinical establishments. The law prescribes minimum standards of facilities and services, for instance, prominently displaying information related to charges of services and availability of facilities at such establishments to ensure accountability. The *Clinical Establishment (Central Government) Rules, 2012* also prescribe that clinical establishments shall charge such rates for every procedure and service within a range as determined and issued by the central government in consultation with state governments, as a condition for registration.

The reported cases on CEA deal with contestation of standards laid under the law by private practitioners and entities. The constitutional validity of the *West Bengal Clinical Establishments (Registration, Regulation and Transparency) Act, 2017* were challenged by medical practitioners who run independent clinics, on grounds of restriction of the freedom of profession under Article 19(1)(g) and arbitrary classification under Article 14 in so far as the law mandates such independent clinics to follow similar minimum standards as larger clinical establishments. Upholding the constitutional validity of the law on both grounds, the court noted that the law provided remedies against widespread malpractice in the state of establishments detaining patients to recover payment for services.<sup>272</sup> Similar challenges to the constitutional validity of CEA have been dismissed, with other High Courts clarifying that the law provides adequate guidance to the government on laying down differential standards for clinical establishments on basis of scale of operations, where deemed appropriate.<sup>273</sup>

In a series of cases, courts have held that when governments grant incentives to private healthcare establishments, like allocation of public land at prices lower than market value, they are entitled to mandate such hospitals to provide treatment free of charge for people living in poverty in the ratio of 10 percent of in-patient care and 25 percent of out-patient care. The authority to impose such public service obligations under contract is derived from the government's responsibility to improve public health under Article 21 and Article 47, and non-compliance of the condition can result in penalty in form of forfeiture of the allotted land.<sup>274</sup>

The Competition Commission of India (CCI), mandated by the *Competition Act, 2002* to regulate anti-competitive market practices, is currently investigating unfair pricing by private super-specialty hospitals, reportedly by compelling patients to purchase drugs and medical devices through in-house pharmacies at higher rates than those in the open market. The CCI investigation will also cover practices of super-specialty hospitals in prescribing goods and services which are not medically necessary or of therapeutic

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<sup>269</sup> Id at 130, *VP Shantha*

<sup>270</sup> Id at 130, *Medicos Legal Action Group* order dt. 25.10.2021

<sup>271</sup> State and UTs (Rules and Notifications). Available at: <http://clinicaestablishments.gov.in/En/1077-state-and-uts-rules-and-notification.aspx>

<sup>272</sup> *Dr. Md. Rezaul Karim v State of West Bengal* AIR 2018 Cal 18

<sup>273</sup> *Dr. Ashwini Goyal v Union of India* 2012 SCC Online Del 3993; *D. Dharmabalan v The Secretary, Dept. of Health and Family Welfare*, order dt. 18.12.2019 of Madras High Court

<sup>274</sup> *Union of India v Moolchand Kharaiti Ram Trust* (2018) 8 SCC 321, *Social Jurist v State (NCT of Delhi)* (2007) 140 DLT 698

benefit to patients.<sup>275</sup>The CCI scrutiny could potentially rein in the prices of medicines and healthcare equipment, or at the very least, bring in transparency in the way hospitals sell these items.

The CCI also regulates the conduct of pharmacies. The directions by associations of wholesalers and retailers of drugs to prohibit retailers from granting discounts on maximum retail price (MRP) of drugs to consumers results in prevention of sale of drugs at prices lower than MRP, penalties and closures on violators and unduly interfering with the supply of drugs in the open market. These acts constitute anti-competitive practices under law and CCI routinely issues cease and desist orders and imposes monetary fines against such associations and directs apex industry bodies like the All India Organization of Chemists and Druggists (AIOCD) to issue circulars to member associations to prevent such unfair practices.<sup>276</sup>

Early in the pandemic, the Supreme Court took note of the catastrophic expenses related to COVID-19 treatments borne by patients in private hospitals and exhorted the government to either scale-up capacity of public healthcare systems or impose price caps on private healthcare sector under authority of the *Disaster Management Act, 2005* (DMA).<sup>277</sup> Accordingly, several state governments issued orders under the DMA, CEA and the *Epidemic Diseases Act, 1897* (EDA) to impose price caps in order to regulate prices of Covid-19 related goods, services and facilities.<sup>278</sup>

The Telangana government issued price cap orders to regulate PPE kits, CT scans, blood tests, oxygen beds, ICU beds, ventilator beds, ambulance charges etc. in private healthcare facilities and the High Court monitored the implementation of the orders by the private sector.<sup>279</sup> Similarly, the Gujarat government issued orders to requisition private healthcare apparatus, including diagnostic centres, for treatment and control of COVID-19 and the High Court monitored the implementation of orders.<sup>280</sup>

However, the private sector opposed regulation at critical junctures during the public health emergency. In a challenge to legal validity of orders issued by the Kerala government that imposed regulations with respect to displaying rates, price caps and supply of essential medicines etc., the High Court declared the measures to be constitutionally valid on basis of the government's obligation to protect the right to health under Article 21 read with the obligation to ensure that privatization does not impede patients' access to healthcare goods, services and facilities as per General Comment 14 to the ICESCR.<sup>281</sup>

In a petition seeking to regulate costs of COVID-19 testing – approved at INR 4,500 by the Indian Council for Medical Research (ICMR) – the Supreme Court initially ordered free testing for everyone in public and private labs under its Article 32 jurisdiction, early in the pandemic. However, on intervention of private industry bodies, the court modified its former order to state that only eligible persons covered by the Ayushman Bharat Pradhan Mantri Jan Aarogya Yojana (AB-PMJAY) and other targeted schemes by state governments shall be entitled to free tests in private labs.<sup>282</sup> The private sector's efforts at diluting the apex court's orders on the limited aspect of diagnostic tests displays a lack of concern for public health, as AB-PMJAY suffers from high exclusion errors in implementation (in addition to exclusion errors in

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<sup>275</sup> *Vivek Sharma v Becton Dickinson India (P) Ltd. and Anr.* Case No. 77 of 2015, order dt. 31.08.2018

<sup>276</sup> *In Re: Bengal Chemist and Drug Association*, Suo Moto Case No. 02/2012, 2014 SCC Online CCI 38

<sup>277</sup> *In Re: The Proper Treatment of Covid-19 Patients and Dignified Handling of Dead Bodies in Hospitals etc.*, Suo Moto WP(C) No. 7/2020, order dt. 18.12.2020

<sup>278</sup> Bhuyan, A. (2020, August 4). Exorbitant Covid-19 treatment prices slashed as State Governments step up. *Indiaspend*. Available at: <https://www.indiaspend.com/exorbitant-covid-19-treatment-prices-slashed-as-state-governments-step-up/>

<sup>279</sup> *Sameer Ahmed v State of Telangana*, WP (PIL) Nos. 56 and 58/2020, order dt. 17.05.2021

<sup>280</sup> *Suo Moto v State of Gujarat*, WP (PIL) No. 42/2020, orders dt. 29.05.2020 and 24.07.2020

<sup>281</sup> *Sabu Joseph v State of Kerala*, WP (C) No. 10659/2021, order dt. 10.05.2021

<sup>282</sup> *Shashank Deo Sudhi v Union of India*, orders dt. 08.04.2022 and 13.04.2020

design) according to the government's own evaluation of the programme.<sup>283</sup> In such a context, the effort to make diagnostic services available for every individual is very likely to have suffered exclusion errors, leading to out-of-pocket expenditure for healthcare services.

The Maharashtra government's experience in regulation of the private sector during COVID-19 also merits attention. By a May 2020 notification, the government regulated and imposed price caps on COVID-19 as well as non-COVID-19 general healthcare goods and services in up to 80 percent of private facilities.<sup>284</sup> The government defended the notification's validity on the assertion that affordability of general healthcare was directly impacted by increase in occupancy of public healthcare facilities for COVID-19-related healthcare needs of patients.

On challenge by the private sector, although the High Court upheld the COVID-19 related regulation, it set aside the measures relating to non-COVID-19 general healthcare on the ground that the measure violated private healthcare practitioners' right to freely practice their profession under Article 19(1)(g).

The court held that the EDA and DMA did not authorize the government to regulate private healthcare establishments who were allegedly charging exploitative prices for general healthcare, since the government failed to substantiate the contention by placing appropriate evidence on record.

The court noted that Entry 6 (public health), List II of Schedule VII does not grant power to state governments to regulate or cap the rates chargeable by private hospitals for general healthcare, therefore, states are not competent to enact laws to this effect.<sup>285</sup> On appeal by the Maharashtra government, the Supreme Court refused to interfere and upheld the High Court's order.<sup>286</sup> While the court's order only records the dismissal of the appeal, the oral remarks across the bench suggest that the court refused to even entertain the matter on merits on the ground that since the public healthcare facilities were unable to provide services, the government could not in such backdrop rein in the private sector which was making up for its shortcomings.<sup>287</sup> This approach fails to take notice of the public interest concern of regulating the private sector notwithstanding the government's inability to fulfil its duty.

In particular, the court's conclusion on the lack of legislative power of states to regulate rates of the private healthcare sector in general on the basis of this Entry is questionable. First, this view militates against settled law that powers under the State List must be given a broad and liberal interpretation to foster autonomy of states in matters allocated to them.<sup>288</sup> Second, General Comment 14 explicitly requires governments to adopt laws to regulate the private healthcare sector.

As constitutional courts interpret Article 12 of ICESCR with Article 21 of the Constitution and apply the doctrine of '*living constitutionalism*', this view must grant the constitutional authority to state governments to regulate the private healthcare sector, which includes price-capping measures. Since the court's order does not take into account this position of law, it is well arguable that it is *per incuriam*, i.e., it is bad in law, and inappropriate precedent to follow by coordinate constitutional courts.

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<sup>283</sup> National Health Authority. (2022). Analysing the effectiveness of targeting under AB PM-JAY in India. Available at: [https://abdm.gov.in:8081/uploads/03\\_Analysing\\_the\\_effectiveness\\_of\\_targeting\\_under\\_PMJAY\\_in\\_India\\_2\\_2d1e276ae3.pdf](https://abdm.gov.in:8081/uploads/03_Analysing_the_effectiveness_of_targeting_under_PMJAY_in_India_2_2d1e276ae3.pdf)

<sup>284</sup> Public Health Department (2020, 21 May), Notification, No. CORONA-2020/C.R.97/Aro-5

<sup>285</sup> *Hospitals Association, Nagpur and others v State of Maharashtra*, WP No. 1936 of 2020, order dt. 20.10.2020

<sup>286</sup> *State of Maharashtra v Hospitals Association, Nagpur*, SLP No. 15147 of 2020, order dt. 19.07.2021

<sup>287</sup> SC rejects Maharashtra plea against order quashing directive capping treatment cost of non-Covid patients, July 19 2021, The Economic Times; available at: <https://economictimes.indiatimes.com/news/india/sc-rejects-maharashtra-plea-against-order-quashing-directive-capping-treatment-cost-of-non-covid-patients/articleshow/84544081.cms>

<sup>288</sup> Id at 180, *International Tourist Corpn.*

The Maharashtra government has since notified the *Maharashtra Nursing Homes Registration Rules, 2021* (MNHRR) under its parent statute, which explicitly provides by a standard charter of patient's rights for nursing homes to display details of all types of rates for various treatments, but not more than as notified by the government regularly. This includes regulation of charges for admission, bed/ICU, doctor consultation, operation theatre, nursing, pathology/radiology/sonography, among others.<sup>289</sup> It is an open question how constitutional courts may review the validity of MNHRR's regulation of private nursing homes in the backdrop of this adverse order.

### 3.2.1.3 Healthcare professionals

The qualifications, conduct and working conditions for healthcare professionals are governed by multiple laws. The issue of working conditions for some categories of healthcare professionals falls within the remit of labour laws. Nurses' associations have petitioned courts seeking regulation of working conditions in private hospitals and nursing homes on matters relating to payment of salaries equivalent to nurses in government hospitals and legal validity of service bonds, among others. In one case, the Supreme Court directed the central government to constitute a committee to deliberate these concerns and frame suitable guidelines or law to redress the grievances.<sup>290</sup> In response to the deliberations by the committee, the NCT of Delhi government issued an order to revise payment of salaries and ensure better working conditions. This order was challenged by private hospitals associations on the ground that revision of nurses' salaries would adversely impact commercial operations of hospitals, and that non-compliance of the order merited cancellation of private hospitals or nursing homes in violation of statutory law. The Delhi High Court agreed with the latter view and set aside the order to the extent the cancellation of registration exceeded applicable statutory law. However, it affirmed the obligation of private hospitals on payment of revised salaries to nurses.<sup>291</sup> It is worthwhile to note that General Comment 14's focus on the 'availability' component of the right to health includes the duty of States to adopt measures for recruitment and retention of adequately trained human resources for healthcare who are paid competitive salaries.

The conduct of healthcare professionals is regulated by civil and criminal law. The standards to determine medical negligence in civil and criminal law are similar, with the exception that criminal proceedings only deal with cases of *gross* negligence which directly result in the death of a patient under section 304A of the *Indian Penal Code, 1860* (IPC). To prevent harassment of medical professionals, courts have added fetters on the ability of an aggrieved party to initiate criminal proceedings. The guidelines developed by courts require the complainant as well as the investigating officer to support its case by medical opinions of independent doctors affirming the view that the defendant has committed gross negligence.<sup>292</sup>

A charge of medical negligence (whether under CPA or IPC) is proved by demonstrating the medical professional has not followed the appropriate standards of care owed to patients, namely, (1) there exists a normal course of practice, (2) the medical practitioner has deviated from said practice, (3) no medical practitioner or ordinary skill would take the impugned course of action and (4) the patient suffers harm directly as a consequence of the breach.<sup>293</sup> It is an established position that hospitals are vicariously liable for acts of medical negligence by treating doctors, and as observed earlier, courts direct payment of compensation for violation of the right to appropriate medical treatment and care under Article 21 as a remedy in such cases.<sup>294</sup> It must be noted that General Comment 14 enjoins States to undertake effective

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<sup>289</sup> Rule 11-Q read with Schedule III of MNHRR

<sup>290</sup> *Trained Nurses Association of India v Union of India* 2016 SCC Online SC 95

<sup>291</sup> *Association of Healthcare Providers (India) v Govt. of NCT of Delhi*, WP(C) 7291/2018, order dt. 24.07.2019

<sup>292</sup> *Jacob Matthew v State of Punjab* (2005) 6 SCC 1

<sup>293</sup> *Maharaja Agrasen Hospital v Rishabh Sharma* (2020) 6 SCC 501; *Vinod Jain v Santokba Durlabhji Memorial Hospital* (2019) 12 SCC 229

<sup>294</sup> See for example, *B. Suvarama Phani v Miot Hospitals IV* (2012) CPJ50(RE)

and appropriate measures (administrative, legislative, judicial and others) to ensure that harmful social norms and practices do not interfere with healthcare decision-making, inflict gender-based violence and violate sexual and reproductive health rights of adolescents as well as adults. Instances of such practices typically include barriers to access pre- and post-natal care, family planning services and female genital mutilation. However, courts must be cognizant of evolving legal standards with respect to medical abuses, for instance, prohibition and punishment of unscientific and harmful practices like conversion therapy against LGBT individuals, irrespective of age and consent.

In matters dealing with regulation of healthcare professionals' conduct with pharmaceutical companies and allied health sector industry, the Supreme Court has declared that the *Indian Medical Council (Professional conduct, Etiquette and Ethics) Regulations, 2002* squarely prohibit medical practitioners from accepting any gifts, travel facilities, hospitality, cash or monetary grants from such commercial entities. A violation of such regulations by medical practitioners can result in sanctions, including suspension of license to practice for a stipulated period. On the other hand, the court has endorsed taking appropriate action against the commercial entities by the Drugs Controller General of India (DCGI) and the Income Tax Department for violation of the regulations. These regulations protect the principle which governs doctor-patient relationships – trust. As such malpractices impact the professional opinion of medical practitioners in favour of prescribing patented and expensive medicines, instead of generic medicines that are equally efficacious and available at cheaper prices, the courts declare such unwarranted interference by commercial entities in decision-making by medical practitioners as against public policy since they prioritize profit over people.<sup>295</sup>

#### **3.2.1.4 Pharmaceutical industry**

Ensuring access to essential medicines is a core obligation under the right to health.<sup>296</sup> It is also specifically identified as a key component of UHC in the SDGs.<sup>297</sup> While measuring progress on UHC, the WHO includes indicators that show both the level and equity of coverage some of which relate to access to medicines and treatment. In the case of infectious diseases this includes access to tuberculosis treatment and HIV antiretroviral treatment.<sup>298</sup>

Several laws and policies impact how people can access affordable medicines. In this section, judicial interventions in two key areas of regulation of the pharmaceutical industry are highlighted that impact the affordability and availability of medicines, medical devices and other health technologies i.e., price control and patents.

##### Price Control

Under Section 3 of the *Essential Commodities Act, 1955* (ECA) the central government is empowered to set price limits on commodities considered essential to the general public. Drug Price Control Orders (DPCO) have been issued under the ECA since 1970, with modifications introduced over time. In *Union of India & Anr v Cynamide India Ltd. & Anr*<sup>299</sup> the central government challenged the quashing of its notification fixing maximum prices for various domestically produced bulk drugs by a High Court on grounds of violation of the principles of natural justice (i.e., giving notice to the manufacturers before the notification). While holding that the issuing of a general notification applicable to all manufacturers amounted to legislative activity which was not subject to the rules of natural justice, the court held that,

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<sup>295</sup> *Apex Laboratories Pvt. Ltd. v Dy. Commissioner of Income Tax* 2022 SCC Online SC 221

<sup>296</sup> Id at 12, *General Comment 14*

<sup>297</sup> Id at 34.

<sup>298</sup> World Health Organisation and The World Bank (2021). *Tracking Universal Health Coverage; 2021 Global Monitoring Report*. p. 62. Available at [https://cdn.who.int/media/docs/default-source/world-health-data-platform/events/tracking-universal-health-coverage-2021-global-monitoring-report\\_uhc-day.pdf?sfvrsn=fd5c65c6\\_5&download=true](https://cdn.who.int/media/docs/default-source/world-health-data-platform/events/tracking-universal-health-coverage-2021-global-monitoring-report_uhc-day.pdf?sfvrsn=fd5c65c6_5&download=true).

<sup>299</sup> 1987 AIR 1802

*“price fixation is neither the function nor the forte of the Court”*<sup>300</sup> and that *“the Court is concerned neither with the policy nor with the rates.”*<sup>301</sup> It did, however, retain the jurisdiction to enquire into whether relevant considerations have gone in and irrelevant considerations kept out of the determination of the price and if there was any hostile discrimination. Identifying the Constitutional basis for price fixing powers of the government, the court held,

*“Profiteering, by itself, is evil. Profiteering in the scarce resources of the community, much needed life-sustaining food stuffs and life-saving drugs is diabolic. It is a menace which has to be lettered and curbed. The Essential Commodities Act, 1955 is a legislation towards that end, in keeping with the duty of the State enshrined in Art. 39(b) of the Constitution towards securing that the ownership and control of the material resources of the community are so distributed as best to subserve the common good. The right of the citizen to obtain essential articles at fair prices and duty of the State to provide them are thus transformed into the power of the State to fix prices and obligation of the producer to charge no more than the price fixed.”*<sup>302</sup>

The court also found that the ultimate aim of the DPCO and of notifications fixing the price of a bulk drug is, *“its equitable distribution and making it available at a fair price for the benefit of the ultimate consumer in consonance with Article 39(b) of the Constitution.”*<sup>303</sup> The primacy of consumer and public interest was also highlighted by the court when it noted that the High Court’s interim order quashing the notification accounted for the interests of the manufacturers but *“the consumer public has been left high and dry.”*<sup>304</sup> The Supreme Court accordingly limited the circumstances when such order can be granted stating that,

*“Where prices of essential commodities are fixed in order to maintain or increase their supply or for securing their equitable distribution and availability at fair prices, the court should not make any interim order staying the implementation of the notification fixing the prices. Such orders are against the public interest and ought not to be made by a court unless it is satisfied that no public interest is going to suffer. In matters of fixation of price, it is the interest of the consumer public that must come first and any interim order must take care of that interest.”*<sup>305</sup>

The decision of the Supreme Court in the *Cyanimide* case, particularly regarding the primacy of public interest underpinning the DPCO, the limited jurisdiction of the court in relation to policy decisions on price fixation and on interim orders have been reaffirmed over the years.

Interestingly, in a decision given shortly before this judgment, the Supreme Court in *Vincent Panikurlangara v Union of India & Ors.*<sup>306</sup> examined a petition for the banning of drugs banned in Western countries. The court held that the magnitude, complexity and technical nature of such an enquiry and its far-reaching implications meant that the court could not go into it. The court did, however, detail the authorities and manner in which the central government could do so and expressed its hope that such an enquiry would take place within six months. While doing so, the Supreme Court also held,

*“...such drugs as are found necessary should be manufactured in abundance and availability to satisfy every demand should be ensured. The State's obligation to enforce production of quality drugs and elimination of the injurious ones from the market must*

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<sup>300</sup> Ibid.

<sup>301</sup> Ibid.

<sup>302</sup> Ibid.

<sup>303</sup> Ibid.

<sup>304</sup> Ibid.

<sup>305</sup> Ibid.

<sup>306</sup> 1987 SCC (2) 165

*take within its sweep an obligation to make useful drugs available at reasonable price so as to be within the common man's reach. That would involve regulating the price. It may be that there may be an improved quality of a particular medicine which on account of its cost of production will have to sell at a higher price but for every illness which can be cured by treatment, the patient must be in a position to get its medicine. This is an obligation under Article 47 of the Constitution.”<sup>307</sup>*

Article 47, it may be recalled, is a DPSP recognising the duty of the government to ensure public health; the Supreme Court in this case noted that simply because DPSPs are not enforceable in a court of law does not mean they do not form a binding duty on the government.

This recognition of the duty of the State to ensure the availability and affordability of necessary medicines has been critical to the engagement of health groups with the DPCO. While manufacturers have regularly challenged notifications under the DPCO, the consistent policy approach of the government to reduce the number of drugs under price control over time has been the subject of PILs by concerned citizens and health groups.

This was the case with the *National Pharmaceutical Policy 2002* (NPP) which health groups contended was going to result in several important drugs falling out of the price control regime. In *Union of India v KS Gopinath & Ors*,<sup>308</sup> the Supreme Court allowed the implementation of the NPP while also directing that the government “*consider and formulate appropriate criteria for ensuring essential and life-saving drugs not to fall out of price control and further directed to review drugs which are essential and life-saving in nature...*” The case was finally dismissed in 2011 when the government informed the court that it was not implementing the 2002 policy.

The issue of price control and essential medicines however remained unresolved. In *All India Drug Action Network (AIDAN) v Union of India*,<sup>309</sup> the court asked the government to file affidavits indicating when it proposed to bring the National List of Essential Medicines (NLEM) 2011 under price control. Eventually, the government issued the DPCO, 2013 bringing the NLEM 2011 under price control. AIDAN continued its case in the Supreme Court arguing that the market-based formula of DPCO, 2013 meant that essential medicines would continue to be unaffordable. In keeping with its line from previous cases, the Supreme Court directed that AIDAN file its objections as a representation and that the central government consider and respond to those objections and file them in court. The final hearing in this matter, since the filing of the representation and the response to it, has been pending since 2019.

The functioning of the National Pharmaceuticals Pricing Authority (NPPA) as an independent statutory authority under ECA has faced intense pressure from both private interest groups as well as the governing ministry.<sup>310</sup> In 2014, the NPPA exercised extraordinary powers under DPCO, 2013 and issued 108 price control orders to regulate prices of drugs beyond the NLEM 2011 (relating to cancer, HIV, diabetes, TB, malaria, cardio-vascular disease, asthma and others), which were contested before courts by industry groups. During the pendency of these cases, the NPPA withdrew its internal guidelines that formed the basis of the orders, under instructions from the Department of Pharmaceuticals (Ministry of Fertilizers

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<sup>307</sup> Ibid.

<sup>308</sup> SLP 3668 of 2003

<sup>309</sup> WP(Civil) No. 423/2003, order dt. 11.10.2011

<sup>310</sup> See for example, India's withdrawal of drug price cap guidelines to be on prospective basis. (2014, September 23). Reuters. Available at:

<https://www.reuters.com/article/india-pharmaceuticals-regulations-idUSL3N0R01WR20140923>



and Chemicals).<sup>311</sup> After considerable criticism in the media of the withdrawal, the central government issued a press release clarifying that the powers of the NPPA had not been withdrawn nor were its price control orders on non-essential drugs. Upholding the validity of NPPA's exercise of powers under DPCO, 2013 on non-essential drugs, the Bombay High Court declared:

*"...market failure alone may not constitute sufficient grounds for Government's intervention, but when such failure is considered in the context of role the pharmaceuticals play in the area of public health, which is a social right, the Government intervention becomes necessary especially when exploitive pricing makes medicines un-affordable and beyond the reach of most and also puts huge financial burden in terms of out of pocket expenditure on healthcare."*<sup>312</sup>

Despite this, the internal guidelines appear to remain withdrawn and prices of non-essential drugs and medical devices at present are largely controlled through a prohibition of more than an annual 10 percent increase in MRP and limits on trade margins.<sup>313</sup> While the courts have largely upheld the exercise of powers by the government in relation to price control, on pleas for bringing additional medicines or medical technologies within the ambit of price control, the courts have stuck to their position of this being a policy matter opting instead to nudge the government into taking action rather than directing it. Thus, the inclusion of medical devices in the NLEM and their price control came at the nudging of courts. In 2016, the MOHFW included coronary stents in the NLEM after the Delhi High Court directed the government to consider as a representation a PIL asking for the inclusion of stents in the NLEM and bringing them under price control.<sup>314</sup>

This approach was continued by the Supreme Court in relation to COVID-19 medicines and treatments. While the court noted that government actions to ensure affordability was a policy matter, it held forth in a recommendatory tone, laying out in detail whether the specific medicines used in the treatment of COVID-19 were in the national protocol, and the various powers at the disposal of the government including emergency powers under the DPCO, and their suggested deployment to control the prices of these medicines.<sup>315</sup> While the government employed a mix of strategies including monitoring of prices, discussions with manufacturers, limits on trade margins and price caps,<sup>316</sup> diagnostics, medicines and medical devices for COVID-19 remained largely unaffordable at the height of the pandemic.<sup>317</sup> In the case of remdesivir for instance, the government informed the Supreme Court that in May 2021, its negotiations with manufacturers had brought the price down by 25-30 percent<sup>318</sup>; prices after this reduction ranged from INR 899 to INR 3490 per vial.<sup>319</sup> It is noteworthy that this price reduction came nearly a year after generic companies in India had started manufacturing remdesivir while estimates suggested that a five-

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<sup>311</sup> National Pharmaceutical Pricing Authority (2014, September, 22), Sub: Internal Guidelines on fixation/revision of prices of schedules and non-scheduled formulations under paragraph 19 of DPCO, 2013 dated 29.05.2014...reg. F. No. 223(01)/2014/Div-III(M&E)/NPPA

<sup>312</sup> *Indian Pharmaceutical Alliance & Anr. v Union of India & Ors.*, WP (C) No. 2700/2014, order dt. 26.09.2016

<sup>313</sup> Ministry of Chemicals and Fertilizers, Department of Pharmaceuticals, National Pharmaceuticals Pricing Authority. (2019, February 27). Order. S.O. 1041(E).

<sup>314</sup> *Birendra Sangwan v Union of India*, W.P.(C) 1772/2015

<sup>315</sup> Id at 98, *In re: Distribution of essential supplies and services during pandemic* order dt. 30.04.2021, para. 55

<sup>316</sup> See for example, Ministry of Chemicals and Fertilizers, Department of Pharmaceuticals, National Pharmaceuticals Pricing Authority. (2021, July 13). Order. S.O. 2808(E).

<sup>317</sup> See for example, Reddy et al. (2021). Direct Medical Cost Analysis of Indian COVID-19 Patients Requiring Critical Care Admission. *Indian J Crit Care Med.* 2021 Oct; 25(10): 1120–1125.

<sup>318</sup> *In Re: Distribution of Essential Supplies and Services During Pandemic*, *Suo Motu Writ Petition (C) No.3/2021*, affidavit dated 09.05.2021 on behalf of the Union of India

<sup>319</sup> Ministry of Chemicals and Fertilizers, Government of India. (2021, April 17). Office Memorandum. File No. 37008/2021/Div.VI/NPPA

day course of remdesivir (6 vials) including a 10 percent profit margin and 27 percent tax should have cost less than INR 500.<sup>320</sup>

### Patents

Patent law is another key area that impacts the availability and affordability of medicines in India. India's reputation and capacity as the pharmacy of the developing world was built largely on the basis of the *Patents Act, 1970* which limited patent rights on food and pharmaceuticals contributing to the development of India's large and diverse generic industry.<sup>321</sup> In 2005, this law was amended to comply with the World Trade Organisation's (WTO) Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) and India started granting 20-year patents on medicines. Patent holders can prevent competitors from making and selling their patented medicines usually resulting in decreased availability and high prices. To address these potential negative impacts of patents, the 2005 amendments to the patent law include several health safeguards.<sup>322</sup> Chief among them is a restriction on the grant of patents on new forms of existing medicines unless there is a significant increase in efficacy.

This provision— Section 3(d) — was challenged before the Supreme Court after it became the basis of the rejection of a key patent application filed by Swiss multi-national company (MNC) Novartis AG on a salt form of *imatinib*, a cancer medicine for the treatment of chronic myeloid leukaemia (CML). In September 2005, the Cancer Patients Aid Association (CPAA) filed a patent opposition challenging Novartis' patent application on a b-crystalline form of imatinib mesylate.<sup>323</sup> While Novartis' global price for the drug was approximately INR 1.2 lakhs per person per month, Indian generic companies sold their versions at far lower prices. The patent office's rejection of Novartis' patent application in 2006<sup>324</sup> set off a series of appeals by the company challenging not only the rejection but also launching a constitutional challenge to the validity of Section 3(d) at the Madras High Court.

Upholding the constitutional validity of the provision, the Madras High Court stated, "*We have borne in mind the object which the Amending Act wanted to achieve namely, to prevent evergreening; to provide easy access to the citizens of this country to life saving drugs and to discharge their Constitutional obligation of providing good health care to its citizens.*"<sup>325</sup> In appeal to the Supreme Court, Novartis challenged the interpretation of section 3(d) rather than the provision itself as it had done before the Madras High Court. The Supreme Court upheld the strict interpretation and application of Section 3(d) in its judgment after examining the history of the provision and noting the Parliamentary debates as well as the letters written by UN agencies to the government expressing their concern of the impact India's new product patent regime would have on global access to affordable medicines. The Court noted that,

*"A perusal of the Parliamentary debate would further reveal that the whole debate centered on medicines and drugs. It would not be an exaggeration to say that eighty per cent of the debate was focused on medicines and drugs and the remaining twenty per cent on agricultural chemicals. In the entire debate, no substance of any other kind came under discussion. The aforementioned amendment in Section 3(d) is one of the most crucial*

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<sup>320</sup> Hill et al. (2020). Minimum costs to manufacture new treatments for COVID-19. *J Virus Erad.* 2020 Apr; 6(2): 61–69. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7331548/>

<sup>321</sup> Sengupta, Amit. (2013, August 10). Two Decades of Struggle. *Economic and Political Weekly*. Vol. 48, No. 32 (AUGUST 10, 2013), pp. 43-45

<sup>322</sup> Ibid.

<sup>323</sup> Cancer Patient Aid Association. Pre-grant Representation by way of Opposition, Re: Patent Application NO. 1602/MAS/98. 22 September 2005. Available at:

[https://www.patentoppositions.org/en/drugs/imatinib/patent\\_oppositions/50063ca98521a20002000006](https://www.patentoppositions.org/en/drugs/imatinib/patent_oppositions/50063ca98521a20002000006)

<sup>324</sup> Dhar and Gopakumar. (2006). Post-2005 TRIPS Scenario in Patent Protection in the Pharmaceutical Sector: The Case of the Generic Pharmaceutical Industry in India. ICTSD, UNCTAD and IDRC. Available at:

[https://unctad.org/system/files/official-document/ictsd-idrc2006d2\\_en.pdf](https://unctad.org/system/files/official-document/ictsd-idrc2006d2_en.pdf)

<sup>325</sup> *Novartis AG v Union of India*, W.P. Nos.24759 and 24760 of 2006

*amendments that saw the Bill through Parliament and, as noted, the amendment is primarily in respect of medicines and drugs and, to some extent, agricultural chemical substances...It is seen above that, in course of the Parliamentary debates, the amendment in Section 3(d) was the only provision cited by the Government to allay the fears of the Opposition members concerning the abuses to which a product patent in medicines may be vulnerable. We have, therefore, no doubt that the amendment/addition made in Section 3(d) is meant especially to deal with chemical substances, and more particularly pharmaceutical products. The amended portion of Section 3(d) clearly sets up a second tier of qualifying standards for chemical substances/pharmaceutical products in order to leave the door open for true and genuine inventions but, at the same time, to check any attempt at repetitive patenting or extension of the patent term on spurious grounds.*<sup>326</sup>

The Supreme Court held that, 'efficacy' in section 3(d) meant "therapeutic efficacy"<sup>327</sup> which must be interpreted strictly and narrowly and therefore Novartis' patent application did not meet the test of the provision. *Imatinib* is presently listed as an essential medicine on the NLEM with a price cap of INR 255.28 per 400 mg tablet for a monthly cost of approximately INR 7656 with several generic versions in the market.<sup>328</sup>

Other provisions of the patent law that have come up before the courts in the context of access to medicines relate to the power of the government to issue compulsory licenses (that allow competitors to manufacture and sell patented medicines) and to revoke patents in public interest. In the case of the first compulsory license issued by the government of India, Natco Pharmaceuticals Ltd. attempted to negotiate a voluntary licensing agreement to manufacture a palliative drug (*sorefanib tosylate*) for kidney and liver cancer that had been patented by German MNC Bayer Corporation in India. When the parties failed to reach an agreement on the voluntary license, the Controller of Patents granted a compulsory license to Natco in 2012.<sup>329</sup> While Bayer sold the drug at INR 2.80 lakhs per month, Natco submitted that it would sell the same drug at INR 8,800 per month in India. After the Intellectual Property Appellate Board (IPAB) upheld the compulsory license, Bayer filed a challenge before the Bombay High Court.

The court took notice of India being a signatory to the *Doha Declaration on TRIPS and Public Health*,<sup>330</sup> which states that TRIPS does not prevent member States from taking measures to protect public health and promote access to medicines for all. It observed that as per the patent law in respect of medicines, the satisfaction of public needs to an adequate extent test has to be 100 percent availability, i.e., to the fullest extent. Medicines have to be made available to every patient and Bayer, the patent holder, failed in meeting this standard under the law. The court held that this was the mandate of Parliament in providing for compulsory licenses under patent law, and such an interpretation would also be in accord with the Doha Declaration. The court further held,

*"The entire basis of grant of compulsory licence is based on the objective that patented article is made available to the society in adequate numbers and at a reasonable price. These are matters of public interest. The law of patent is a compromise between interest of the inventor and the public. In this case, we are concerned with patented drug i.e.*

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<sup>326</sup> *Novartis AG & Ors. v Union of India & Ors.* AIR 2013 SC 1311

<sup>327</sup> *Ibid.*

<sup>328</sup> Ministry of Chemicals and Fertilizers, Department of Pharmaceuticals, National Pharmaceuticals Pricing Authority. (2022). Compendium of Ceiling Prices of Scheduled Drugs as on 10.08.2022. Available at: <https://www.nppaindia.nic.in/wp-content/uploads/2022/09/Compendium-Prices-2022.pdf>

<sup>329</sup> Controller of Patents. In the matter of Natco Pharma Limited and Bayer Corporation. Compulsory License Application No. 1 of 2011. Order dt. 09.03.2012.

<sup>330</sup> Fourth WTO Ministerial Conference, Doha Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2 (2001)

*medicines to heal patients suffering from cancer. Public interest is and should always be fundamental in deciding a lis between the parties while granting a compulsory licence for medicines/drugs.*<sup>331</sup>

An appeal against this judgment was dismissed by the Supreme Court.<sup>332</sup> Since this case, no other compulsory licenses have been issued by the government. Some cases have gone before the courts asking for compulsory licenses to be issued or for patents to be revoked in public interest. In these cases, the courts have reiterated their stance of not intervening in policy decisions. Still, as described below, courts have taken different approaches in attempting to push the government towards exercising these powers, albeit to no avail.

In the case of a drug called *indacaterol*, used for the treatment of respiratory diseases like Chronic Obstructive Pulmonary Disease (COPD), Novartis filed a suit for permanent injunction against Cipla Ltd. to restrain it from infringing its patent on indacaterol.<sup>333</sup> The Novartis version was priced at INR 677 per capsule while Cipla's version was INR 130 per capsule.

The court observed that the 'public interest doctrine' would guide courts' grant of injunctions and determination of issues of patent law, especially where life-saving medicines are involved and could impact public health. In suitable cases, the attempt of the court will be to reach an agreement between the infringing/third party and the patentee to continue manufacturing the life-saving drugs locally, instead of completely prohibiting the infringing/third party. The court noted that COPD kills more than 3 million people in India annually, 84 percent of direct costs involved in COPD treatments are for patient hospitalizations and estimated economic losses arising out of COPD is around INR 35,000 crores.

The court concluded that the public health implications of this case outweigh the patentee's commercial interests, therefore, a suitable relief other than a strict injunction needed to be developed to balance the competing interests, i.e., commercial interests of the patentee and public health of Indian population. The court passed a conditional interim injunction whereby it permitted Cipla to file an application for compulsory license, and in the interim period temporarily restrained it from manufacturing the drug until final determination of the license plea. Cipla filed a representation with the government to revoke Novartis' patent but reportedly withdrew the representation.<sup>334</sup> Additionally, it appears that Cipla did not pursue the option of filing for a compulsory license. Its attempt to get the temporary injunction lifted also did not succeed with a division bench of the Delhi High Court holding that considerations of affordability and availability had to be considered by the government in the context of compulsory licenses or other proceedings and in the absence of such proceedings the injunction against Cipla would continue.<sup>335</sup>

In the case of two drugs for the treatment of MDR-TB, *bedaquiline* and *delamanid* have been patented under India's amended patent regime by US MNC Johnson and Johnson Pvt. Ltd. and Japanese MNC Otsuka Pharmaceutical respectively. With both drugs under patent, access has been dependent on 'compassionate use' programmes, donation programmes or the tiered prices set by the patent holders. Such conditional access to life-saving drugs is severely restricted and delays in treatment have resulted in avoidable deaths in India, despite attempts at litigating the legal and administrative barriers to access.<sup>336</sup>

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<sup>331</sup>*Bayer Corporation v Union of India* AIR 2014 Bom 178

<sup>332</sup> Mukherjee, R. (2014, December 13). SC dismisses Bayer plea against generic drug. Time of India.

<sup>333</sup> *Novartis AG & Anr. v Cipla Ltd.* (2015) 216 DLT 689

<sup>334</sup> Rathod S. (2017). Compulsory licences on pharmaceutical patents in India: A short article. *Journal of Generic Medicines* 2017, Vol. 13(3) 108–113

<sup>335</sup> *Cipla Ltd v Novartis AG & Anr* 2017 (70) PTC 80 (Del)

<sup>336</sup> Id at 162, *Kaushal Kishore Tripathi* order dt. 18.01.2017

Health groups have been concerned with the slow rollout of MDR-TB drugs in India as a result of the limited availability of these medicines.<sup>337</sup>In 2021, several reports of the stock-out of *delamanid* were reported.<sup>338</sup>Subsequently, a PIL was filed before the Bombay High Court asking for the court to issue compulsory licenses on these drugs. The court gave the government until 28 April 2021 to make a decision on the representation for the issuance of the compulsory licenses.<sup>339</sup> After, the Department of Promotion of Industry and Internal Trade rejected the representation, the case is now proceeding with a challenge by petitioners against the rejection.<sup>340</sup>

Even as the compulsory license case continues, the patents on the compounds for both drugs expire this year i.e. in 2023. In a significant victory, an evergreening patent application on the fumarate salt of *bedaquiline* has been rejected based on pre-grant oppositions filed by the Maharashtra Network of People living with HIV/AIDS (NMP+) and two TB survivors.<sup>341</sup> An evergreening patent already granted on *delamanid* is unlikely to block generic production.<sup>342</sup>The high possibility of generic versions of both MDR-B drugs will have a considerable impact on both availability and affordability. For instance, the government of India is reportedly paying USD 1271 per 6-month course of *delamanid*.<sup>343</sup> Estimated generic prices (depending on volumes and inclusive of profit margins ranging from 10 percent to 50 percent depending on the volumes) could range from USD 29.6 to USD 243.6 per 6-month course of *delamanid*.<sup>344</sup> Meanwhile the lowest price for *bedaquiline* is USD 272 per 6-month course<sup>345</sup> while generic prices could range from USD 48 to USD 102 for a 6-month course.<sup>346</sup> Despite these developments, the compulsory license case on both drugs would continue to be important as other patents and patent applications on both drugs may impact the ability of generic companies to use efficient processes for the production of the drugs and the introduction of paediatric versions.<sup>347</sup>

The issue of compulsory licensing has also arisen in the case of COVID-19 treatments and vaccines. The Supreme Court in its *suo moto* petition noted that several COVID-19 treatments like remdesivir, favipiravir and tocilizumab are patented and went into considerable detail on the powers of the government to issue compulsory licenses. Still, it concluded by saying that this was a policy decision of the government, which was free to decide which measures to pursue keeping in mind the public interest and the crisis.<sup>348</sup> Not only were no compulsory licenses related to COVID-19 issued, the government issued a press release stating that vaccine manufacturing required licensing and technology transfer and not compulsory

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<sup>337</sup> Chintan, R (2021, October 28). India's fight against TB: Govt's eerie silence over worsening situation, drug stock-outs. Peoples Dispatch.

<sup>338</sup> Mukherjee, R. (2021, October 21). Shortage of key TB drug stress patients; activists urge govt. Times of India.

<sup>339</sup> *Meera Yadav v Union of India*, PIL (L) No. 495/2021, order dt. 10.03.2021

<sup>340</sup> *Meera Yadav & Anr. v Union of India, through the Central TB Division & Ors.*, Public Interest Litigation No. 16 of 2022, order dt. 04.04.22

<sup>341</sup> Controller of Patents, Patent Office Mumbai. (2023, March 23). Decision. *In the matter of the Patents Act, 1970 (as amended) & the Patents Rules, 2003 (as amended) and In the matter of Patent Application No 1220/MUMNP/2009 by JANSSEN PHARMACEUTICA N.V., Belgium and In the matter representation by way of opposition under Section 25 (1) of the Patents Act by Network of Maharashtra people living with HIV And Nandita Venkatesan and Phumeza Tisile.*

<sup>342</sup> Médecins Sans Frontières Access Campaign. (2022). DR-TB Drugs Under the Microscope 2022. 8th Edition

<sup>343</sup> Porecha, M. (2021, December 6). Anti-TB drug Delamanid fast drying out, Centre yet to receive new stocks from Japan. The Hindu Business Line

<sup>344</sup> Goatham et al. (2017). Estimated generic prices for novel treatments for drug-resistant tuberculosis. *Journal of Antimicrobial Chemotherapy*, Volume 72, Issue 4, April 2017, Pages 1243–1252

<sup>345</sup> StopTB Partnership. Global Drug Facility. (2020) FAQs on bedaquiline price reduction and free goods.

<sup>346</sup> Goatham et al. (2017). Estimated generic prices for novel treatments for drug-resistant tuberculosis. *Journal of Antimicrobial Chemotherapy*, Volume 72, Issue 4, April 2017, Pages 1243–1252

<sup>347</sup> Médecins Sans Frontières Access Campaign. (2022). DR-TB Drugs Under the Microscope 2022. 8th Edition

<sup>348</sup> Id at 92, *In re: Distribution of essential supplies and services during pandemic* order dt. 30.04.2021

licenses<sup>349</sup> contradicting its own stand at the international level while proposing a TRIPS waiver at the WTO.<sup>350</sup>

It remains to be seen if the courts will take a more direct approach to compulsory licenses as more and more patients approach the courts for access to expensive patented medicines. The Kerala High Court is currently hearing a petition by a woman diagnosed with breast cancer, who has demanded the issuance of a compulsory license for the excessively priced drug *ribociclib* (INR 58,410 per month). While the woman has succumbed to her illness, the court has decided to hear the matter *suo moto* as it concerns the issue of exorbitant prices of life saving medicines.<sup>351</sup> In December 2022, the central government reportedly submitted to the court that the situation was not one of a national emergency or extreme urgency.<sup>352</sup> Not only does this response appear to ignore the seriousness of breast cancer in India, it also appears to ignore other grounds on which the government can take action including public non-commercial use under section 92 of the Patents Act and government use under section 100. The High Court has now directed the central government to submit data on breast cancer in India.<sup>353</sup>

The CCI has rarely intervened in the pharmaceutical sector on matters related to access to affordable medicines. The first case concerned a complaint by a person living with HIV who sought an investigation into anti-competitive practices by US Gilead Sciences Inc. (USA) and the Medicines Patent Pool (MPP – a Swiss non-profit organization) with respect to the production, sale and marketing of anti-retroviral treatment (ART) for HIV in India. The complaint alleged that the licensing agreements between Gilead and Indian licensees, brokered via MPP, limited the purchase and sale of the active pharmaceutical ingredient (API) exclusively from the American manufacturer, which controlled the price of the API and resultantly made the production of ART prohibitively expensive for those in India who access treatment from the private sector. Additionally, it was also alleged that the patent pooling system (MPP) was restrictive as it locked the technology and production in the control of few parties, thereby making it difficult for parties outside the system the opportunity to produce, sell and market ART drugs and limiting the availability of lifesaving medicines. The CCI dismissed the complaint based on the wholly inadequate consideration that NACO's procurement plan showed that the government has managed treatment access with relative ease, without delving into the impact of the impugned practices on the open market.<sup>354</sup>

The CCI is currently adjudicating a dispute among competing pharmaceutical companies on anti-competitive practices involving a breast cancer drug (*trastuzumab*). Biocon Limited and Mylan Pharmaceuticals Pvt. Ltd. allege that F. Hoffman La Roche's acts of adopting excessive pricing of the drug (INR 75,000 per 150 mg vial) and preventing market entry by spreading misinformation about their biosimilar drugs (cheaper by 25-50 percent on a range of doses) among regulators, doctors and general public constitute abuse of a dominant position under the law. The CCI has sanctioned an enquiry on both aspects, however, it's initial opinion on the unfair pricing is a cause for concern as it has framed the issue of Roche's 'initial' high prices as a "reward for innovation" under the assumption that Roche invested huge sums on research and development (R&D) of the drug.<sup>355</sup>

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<sup>349</sup> Niti Ayog. (2021, May 27). Myths & Facts on India's Vaccination Process. Press Information Bureau. Available at: <https://pib.gov.in/PressReleasePage.aspx?PRID=1722078>.

<sup>350</sup> World Trade Organisation. (2020, October 2). Waiver From Certain Provisions of the Trips Agreement for the Prevention, Containment and Treatment of COVID-19. Communication From India and South Africa. Available at: <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?Filename=q:/IP/C/W669.pdf>

<sup>351</sup> *Smt X v Union of India*, WP(C) No. 18999/2022, order dt. 16.09.2022

<sup>352</sup> Koshy, J. (2022). Government says breast cancer not a matter of 'national' or 'extreme' urgency. The Hindu.

<sup>353</sup> *Smt X v Union of India*, WP(C) No. 18999/2022, order dt. 05.04.2023

<sup>354</sup> *Manoj Hirasingh Pardeshi v Gilead Sciences Inc. USA*, Case No. 41/2012, order dt. 05.03.2013

<sup>355</sup> *Biocon & Anr. v F. Hoffmann-La Roche AG & Ors.*, Case No. 68 of 2016, order dt. 21.04.2017

The basis for this observation by the CCI is unclear. It has become increasingly evident that public funding usually has a strong role to play in the initial R&D of many drugs.<sup>356</sup> In the case of *trastuzumab*, the development and initial studies for the drug were led by the University of California, Los Angeles (UCLA) with funding from public and private sources other than the company that developed the drug, Genentech.<sup>357</sup> Genentech was acquired by Roche in 2009 and has since been earning well over USD5 billion annually from the sales of *trastuzumab*.<sup>358</sup> This annual revenue for Roche is nearly double the highest (and much contested) industry estimate of R&D costs for drug development.<sup>359</sup> Interestingly, the South African Competition Commission recently decided to prosecute Roche for excessive pricing of the same drug. A central aspect of its decision is the application of South Africa's Bill of Rights to competition law, which focused the enquiry on women's right to access lifesaving medicines over "rewards for innovation".<sup>360</sup>

In relation to the pharmaceutical sector, the tension between the need for affordable access to medicines and other health technologies and the interests of the industry are evident. The challenges faced by the judiciary and regulatory bodies in balancing public and private interest in this area highlight the need for these bodies to engage more robustly with the right to health framework.

### **3.2.2 Horizontal application of fundamental rights to the private sector**

An emerging body of jurisprudence postulates that private persons or bodies are covered by constitutional law principles in Part III. This application of law is referred to as the horizontal application of fundamental rights, i.e., private persons or bodies owe the duty to respect rights of the other, as opposed to the conventional view that the government is the guarantor of protection of fundamental rights of persons and is liable in case of violation, i.e., vertical application. We review key propositions here to illustrate applicability of this body of law to affix responsibilities on the private healthcare sector.

Courts have clarified that the form of a concerned body is immaterial. The more appropriate consideration is the nature of the duty imposed on the body. The words 'any person or authority' used in Article 226 are, therefore, not to be confined only to statutory or administrative authorities. It covers *any* other person or body performing 'public duty/function'.<sup>361</sup> It is an established proposition that healthcare and education are treated as 'public duties'/functions' as per constitutional law, in that these sectors have a significant impact on public well-being and capabilities. Courts have explained the jurisprudential basis of this legal principle as such:

*"Judicial review is designed to prevent the cases of abuse of power and neglect of duty by public authorities. However, under our Constitution, Article 226 is couched in such a way that a writ of mandamus could be issued even against a private authority. However, such private authority must be discharging a public function...The role of the State expanded*

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<sup>356</sup> Clearly, E.G., et al (2018), Contribution of NIH funding to new drug approvals 2010-2016, *Proceedings of the National Academy of Sciences*: <https://www.pnas.org/doi/10.1073/pnas.1715368115>

<sup>357</sup> UCLA Jonsson Comprehensive Cancer Centre (2021), Coal Miner's Son: Dr. Slamon, D., *Cancer History Project*: <https://cancerhistoryproject.com/people/coal-miners-son-dr-dennis-slamon>

<sup>358</sup> Kelland, K., (2012), Roche's breast cancer franchise boosted by trial data, *Reuters*: <https://www.reuters.com/article/us-roche-herceptin-idUSBRE8900RW20121001>

<sup>359</sup> DiMasi J.A., et al (2016), Innovation in the pharmaceutical industry: new estimates of R&D costs, *National Library of Medicine* : <https://pubmed.ncbi.nlm.nih.gov/26928437/>

<sup>360</sup> Competition Commission prosecutes a multi-national healthcare company, Roche, for excessive pricing of a breast cancer treatment drug, available at: <https://www.compcom.co.za/wp-content/uploads/2022/02/COMPETITION-COMMISSION-PROSECUTES-A-MULTINATIONAL-HEALTHCARE-COMPANY-ROCHE-FOR-EXCESSIVE-PRICING-OF-A-BREAST-CANCER-TREATMENT-DRUG.pdf>

<sup>361</sup> *Andi Mukta Sadguru Shree Mukta Jeevandas Swami Suvarna Jayanti Mahotsav Smarak Trust v VRRudani* (1989) 2 SCC 691

*enormously and attempts have been made to create various agencies to perform the government functions... At the same time, there are private bodies also which may be discharging public functions.*

*It is difficult to draw a line between the public functions and private functions when it is being discharged by a purely private authority. A body is performing a “public function” when it seeks to achieve some collective benefit for the public...Bodies therefore exercise public functions when they intervene or participate in social or economic affairs in the public interest.*

...

*For instance, a body is performing a public function when it provides “public goods” or other collective services, such as healthcare, education and personal social services, from funds raised by taxation.*

...

*Public functions need not be the exclusive domain of the state. Charities, self-regulatory organizations and other nominally private institutions (such as universities, the Stock Exchange...churches) may in reality also perform some types of public function...Non-governmental bodies such as these are just as capable of abusing their powers as is government.*

...

*A writ of mandamus can be issued against a private body which is not a State within the meaning of Article 12 of the Constitution and such body is amenable to the jurisdiction under Article 226 of the Constitution and the High Court ... can exercise judicial review of the action challenged by a party”<sup>362</sup>*

This constitutional principle, among other grounds, formed the basis of the Gujarat High Court’s regulation of the state’s private healthcare sector early in the pandemic.<sup>363</sup> By taking into consideration that the private hospitals, clinics and nursing homes provide 70 percent of healthcare in India, as per the National Sample Survey Office’s (NSSO) latest estimates, the Gujarat High Court laid down the duties of the private healthcare sector to support the public health effort, in terms of fixing and standardization of prices of healthcare goods, services and facilities.

Certain Articles from Part III of the Constitution are expressly applied as horizontal, in order to evolve legal redress. Article 15(2) states the obligations of private parties of not subjecting a citizen to any disability, liability, restriction or condition regarding access to shops, public restaurants, use of wells, tanks, bathing *ghats* and roads etc on basis of religion, race, caste, sex or place of birth. Thus, Article 15 imposes obligations to respect individual rights on both state and non-state actors. Similarly, Article 17 abolishes untouchability and declares it to be an offence and Article 23(1) that prohibits trafficking in human beings and *begar* (forced labour) recognizes the obligation flowing from both state and non-state actors. Therefore, Articles 15(2), 17, 19, 21 and 23 of the Constitution acknowledge the horizontal nature of these fundamental rights.<sup>364</sup>

A seminal decision that advanced the discourse of horizontal application of fundamental rights concerned the question whether private unaided medical education institutions have a duty to follow public service obligations –in this case, reservation for socially and educationally backward classes (SEBC) of citizens, Scheduled Castes or Scheduled Tribes (SC/ST), as sanctioned by Article 15(5). The Supreme Court held in

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<sup>362</sup> *Binny Limited v V. Sadasivan*, (2005) 6 SCC 657

<sup>363</sup> Id at 280, *Suo Moto v State of Gujarat* order dt. 22.05.2020

<sup>364</sup> *Dr. Sanghamitra Acharya v NCT of Delhi* 2018 SCC Online Del 8450; *Kaushal Kishor v State of Uttar Pradesh*, 2023 SCC Online SC 6



the affirmative and explained the legal basis of covering private actors in reference to the definition of 'shops' in Article 15(2).<sup>365</sup> The court relied on Dr. BR Ambedkar's commentary on Article 15(2) from the constituent assembly debates, in particular, when a query was posed as to whether 'shop' includes a doctor or lawyer's services:

*"To define the word 'shop' in the most generic term one can think of is to state that 'shop' is a place where the owner is prepared to offer his service to anybody who is prepared to go there seeking his service....Certainly it will include anybody who offers his services. I am using it in a generic sense. I should like to point out therefore that the word 'shop' used here is not used in the limited sense of permitting entry. It is used in the larger sense of requiring the services if the terms of service are agreed to."<sup>366</sup>*

In other parts of the constituent assembly debates on Article 15(2), members explain its broad scope for serving the purpose of assimilation of women, SC/ST and other marginalized communities of society, who were historically excluded, in the full range of social and economic affairs of a constitutional democracy. Such a radical application of constitutional provisions to remedy current disputes is labelled as developing a framework of 'transformative constitutionalism',<sup>367</sup> and it is an open question as to how consistently the judiciary will employ this framework to ensure accountability in the area of the private health sector. As courts are boldly venturing beyond the prohibited grounds of discrimination listed under Article 15 (caste, religion, sex) and evolving analogous grounds of discrimination (genetic conditions, sexual orientation, gender identity)<sup>368</sup> by a comprehensive reading of the equality and anti-discrimination mandate of Articles 14-15 with Article 21, the redressal of price discrimination in the private health sector is worth exploring through this prism since healthcare is an established area of regulation under the doctrines of public duty and horizontal application of fundamental rights.

Meanwhile, there is a growing trend of horizontal application of fundamental rights by courts in a range of areas of interest. On this basis, courts have imposed financial liability on private healthcare providers, ambulance service providers and others for committing a woman in a mental healthcare institution without informed consent and violating her bodily integrity by offering medical treatment against her wishes, under Articles 15 and 21.<sup>369</sup>

Courts have affixed financial liability on private airline carriers for de-boarding, undignified and discriminatory treatment by staff towards persons with disabilities and monitored framing of revised guidelines by the Directorate General of Civil Aviation (DGCA) on granting appropriate assistance to persons with disabilities during air travel, under Articles 15 and 21.<sup>370</sup> In doing so, the court held that conventional policies on disability have focussed only on healthcare needs of persons with disabilities, which is inadequate to remedy their marginalization, thereby underscoring the need for policies to include anti-discrimination measures, positive rights, affirmative action and reasonable accommodation.<sup>371</sup>

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<sup>365</sup> *Indian Medical Association v Union of India*, (2011) 7 SCC 179

<sup>366</sup> Constituent Assembly Debates – Vol. VII (29 November 1948), Parliament of India

<sup>367</sup> Horizontal Discrimination and Article 15(2) of the Indian Constitution: A Transformative Approach, Bhatia, G., *Asian Journal of Comparative Law*, 11 (2016) pgs.87-109

<sup>368</sup> Reading Swaraj into Article 15: A New Deal for All Minorities, Khaitan, T., 2 *NUJS L. Rev.* 419 (2009)

<sup>369</sup> *Id* at 364, *Dr. Sanghamitra Acharya*

<sup>370</sup> *Jeeja Ghosh & Ors. v Union of India* (2016) 7 SCC 761

<sup>371</sup> *Ibid.*

Court guidelines governed the area of redressal of sexual harassment in the workplace (public and private) and fostering gender sensitive workplaces on basis of Articles 15, 19 and 21<sup>372</sup> much before Parliament devised a statutory remedy.<sup>373</sup>

Similar to the mode of IRDA regulations imposing statutory and constitutional obligations on private health insurance providers, courts have held that bodies registered under appropriate statutory laws must comply with constitutional norms, as the statutory authorities are mandated to ensure the bodies act in accordance with “applicable law in the territory of India”, as a general condition of registration. Trade unions are therefore prohibited from excluding women from seeking membership on the ground of non-discrimination on basis of sex under Article 15.<sup>374</sup>

However, certain areas like housing remain immune from such regulation till date, on the specious pretext of ‘voluntary association’ of cooperative housing societies being exempt from constitutional scrutiny. As such, courts have failed to mandate that cooperative housing society regulations must prohibit denial of accommodation on the basis of religious affiliation of individuals.<sup>375</sup> Such instances signal the need for a comprehensive anti-discrimination bill that covers private transactions and sectors in all areas of social and economic life.

As evidenced, courts advance novel interpretations of law to evolve remedies to protect fundamental rights. The pandemic has brought the recognition of healthcare as a public good to the forefront, under our constitutional philosophy. This has made courts interpret statutory laws, rules and regulations in conformity to the right to health framework under Article 21 so as to provide accountability for violations of availability, accessibility, acceptability and quality of healthcare goods, services and facilities in the private healthcare sector.

#### 4. CONCLUSION

The right to health is a fundamental right guaranteed under Article 21 of the Constitution, as illustrated by the review of jurisprudence in this paper. Substantive orders of constitutional courts amply demonstrate the wide-ranging powers to issue directions to central and state governments in service of realization of this right. Therefore, any health-related law, programme and policy by the government must be cognizant of judicial review of such measures on grounds of protection or denial of fundamental rights guaranteed under the Constitution. Indeed, in recognition of the inextricable links between maternal health and food security programmes, the rights-based approach mandates that a system of UHC must have linkages with underlying determinants of health by providing for multi-sectoral convergence between the public healthcare system and non-health departments like water, sanitation and housing, among others.

In pursuit of its obligations, it is clear that the Indian government is mandated by legally binding commitments emerging from a robust foundation in domestic law and international human rights law. Further, constitutional courts read international law to interpret the scope of fundamental rights under the Constitution in order to provide expansive protection for the right to health. As just two examples, the nature of obligations of member States under General Comment No. 14 to ICESCR has formed the basis of judicial and policy interventions on developing the *National Policy for Rare Diseases, 2021* as well as regulation of the private sector during COVID-19 in regulating the prices of essential medicines, diagnostics, healthcare goods and healthcare services.

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<sup>372</sup> *Id* at 62, *Vishaka*

<sup>373</sup> *Sexual Harassment of Women at Workplace (Prevention, Prohibition and Redressal) Act, 2013*

<sup>374</sup> *Charu Khurana v Union of India* (2015) 1 SCC 192.

<sup>375</sup> *Zoroastrian Cooperative Housing Society Ltd. v District Registrar, Cooperative Societies (Urban)*, (2005) 5 SCC 632

The central and state governments' joint exercise of power in the area of health has been inconsistent, and on an *ad hoc* basis, resulting in governance uncertainty. This is demonstrable in the central government on the one hand initially foisting financial responsibility for prevention and treatment of rare diseases on state governments which lead to protests by several of the latter, and on the other hand shrugging off responsibility for human rights violations in implementation of the family planning programme. The Supreme Court, as the authoritative interpreter of the Constitution, has unmistakably clarified the position with respect to central and state governments' responsibilities in matters of health, laying out an approach of coordination and negotiation as essential to the successful implementation of healthcare programmes on basis of their powers under the Constitution's Schedule VII.

Lastly, an examination of the governance framework regulating the private sector reveals incremental efforts by constitutional courts in ensuring accountability by applying a rights-based framework to areas of health insurance, responsibilities of healthcare establishments, duty of care by medical professionals and market interventions in drug pricing. Across the country, constitutional courts have generally pushed forward the right to health framework in mandating the government to ensure accountability of the private health sector and granted relief to patients and affected parties. Although the foundational basis of horizontal application of fundamental rights to non-State actors is very promising, it merits deeper exploration for applicability to the private healthcare sector on the issues reviewed herein. Additionally, the mixed experience of regulatory bodies like CEA, NPPA, CCI, IRDA and others highlights these bodies must evolve a practice of performing their regulatory functions through the lens of a rights-based framework, as the review of cases herein establishes that every public authority is bound to perform their functions in a manner consistent with the fundamental right to health under extant law. They must engage more robustly with the right to health framework in order to effectively regulate the private sector with respect to its duty to protect patients' right to access lifesaving medicines, diagnostics and treatments as mandated by the General Comment No. 14 read with Article 21.

As the final recourse for protection of fundamental rights under India's constitutional democracy, courts also serve the function of a public record for contestation of rights by the people against State and non-State actors. As is apparent during the pandemic, for every government failure or inaction, courts' oversight has at the minimum brought accountability on record and encouraged remedial action under binding directions or amicably resolving matters in public interest. Any UHC programme that is conceived needs to answer to the right to health standards traversed in this paper, robustly enriched as they are by the judiciary.

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