REVIEW

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Health legislation and policy:
a focus on disability

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The provision of comprehensive health and social services to those with disabilities requires intersectoral action by both the health and other sectors, as has been outlined in the Framework and Strategy for Disability and Rehabilitation Services in South Africa 2015-2020.

This chapter provides a brief but critical examination of the legislative and policy steps taken towards achieving universal health coverage in South Africa, with particular emphasis on equity and the extent to which adequate provision is made for the services needed by persons with disabilities.

The year 2020 has been dominated by the COVID-19 pandemic. In this context, the position of persons with disabilities is particularly critical. From a legislative point of view, the health systems response has relied largely on existing provisions, and while minor changes have been made, few novel policies or legal instruments have been developed.

Legislation and policy that is of general application to the health sector is also examined. Progress on the National Health Insurance Bill has been limited, due in part to the disruption caused by the COVID-19 pandemic. Further public hearings in the Portfolio Committee on Health will be held before the Bill proceeds to the National Council of Provinces. Other developments include publishing of the draft Social Service Practitioners Bill and referral of the Copyright Amendment Bill (Bill 13 of 2017) back to Parliament. Access to cannabis and cannabis-based medicines remains highly contested. The Cannabis for Private Purposes Bill was approved by Cabinet and tabled in Parliament, and is expected to progress in 2021.

A brief summary of selected health-related secondary and tertiary legislation is also provided, and major health-related jurisprudence related to the councils is discussed.

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Introduction

Universal health coverage (UHC) implies that all people and communities are able to access the promotive, preventive, curative, rehabilitative and palliative health services they need, in ways that are equitable, that ensure the quality of such services, and that protect them from financial harm. Central to UHC is the concept of equity in health – often defined as "the absence of systematic disparities in health … between groups with different levels of underlying social advantage/disadvantage – that is, wealth, power or prestige".[1] In this milieu, persons with disabilities are at a further disadvantage regarding their health needs. According to the World Health Organization (WHO),[2] about 15% of the world's population lives with some form of disability, and these persons have less access to healthcare services, resulting in significant unmet healthcare needs. The provision of comprehensive health and social services to those with disabilities requires intersectoral action by both the health and other sectors, as has been outlined in the Framework and Strategy for Disability and Rehabilitation Services in South Africa 2015-2020.[3]

The Constitution makes only one explicit mention of disability, in section 9(3): "The state may not unfairly discriminate directly or indirectly against anyone on one or more grounds, including race, gender, sex, pregnancy, marital status, ethnic or social origin, colour, sexual orientation, age, disability, religion, conscience, belief, culture, language and birth".[4] This is a particularly strong protection, based on the presumption that the discrimination is unfair unless established otherwise. The Department of Social Development is responsible for protecting the rights of vulnerable sectors of our society, including children, persons with disabilities, and older people. It is also the custodian of international treaties that the country has ratified, such as the Convention on the Rights of Persons with Disabilities, 2007.[5] However, despite issuing the White Paper on the Rights of Persons with Disabilities in 2015, the Department has not promulgated disability-specific legislation.[6]

The 2015 Framework and Strategy identified a number of legislative instruments of relevance to disability, but did not propose any legislative amendments. Implementing the policy requires close attention to a number of health systems barriers, within the current structure for the delivery of health services.[7] The overarching legislation for health, the National Health Act (Act 61 of 2003) (NHA)[8], makes reference to disability in several sections: sections 2 (Objects of Act); 4 (Eligibility for free health services in public health establishments); 39(2) (a) and (d) (Regulations relating to certificates of need); 70 (Identification of health research priorities); and 73 (Health research ethics committees). The global standard, enshrined in article 12 of the International Covenant on Economic, Social and Cultural Rights, recognises the right to the enjoyment of the highest attainable standard of physical and mental health.[9] In this light, the cursory treatment of disability rights in the National Health Insurance (NHI) Bill (Bill 11 of 2019) is all the more disconcerting.[10] There is only one reference to disability, in section 57 (Transitional arrangements). Thus, although the constitutional protection against discrimination would apply, the health rights and concerns of this vulnerable group are not adequately catered for in the Bill. The NHI Bill has not progressed beyond the National Assembly. The Portfolio Committee on Health has held several high-profile hearings in the provinces, and has scheduled an extensive series of virtual public hearings to inform the deliberations.[11] Some 121 groups and individuals have expressed an interest in delivering oral inputs, and the committee had received more than 64 000 written submissions after the call for comments in August 2019.[12] Before this section 76 Bill is referred to the National Council of Provinces (NCOP), the provincial legislatures may also need to repeat public hearings in each province in order to inform the mandates they issue for subsequent deliberations in the NCOP. The real challenges, though, lie with the design of the benefit package, and the contracting of service providers. As Morris et al. point out: "For the NHI to truly be successful in ensuring affordability, and equity in accessing rehabilitation for all South Africans with chronic illness and disabilities, there needs to be major re-evaluations in the redistribution and allocation of government funding towards addressing the shortcomings, i.e. increasing staff and resources within the communities where rehabilitation is needed the most".[7]

The limitations of existing legislation, such as the Mental Health Care Act (Act 17 of 2002),[13] were cruelly exposed in the Life Esidimeni tragedy, where inadequate oversight of under-resourced and neglected mental health services led directly to the violation of the human rights of persons with intellectual and psychosocial disabilities.[14] The explanatory memorandum to the NHI Bill notes that amendments may be required to the Mental Health Care Act, and the Bill mentions that this will be done in Phase 2 (section 57(4)(h)), but no details are provided. The Bill envisages that in phase 1, the NHI Fund will cover healthcare services for the aged and persons with disabilities. School health services are also included, which the explanatory memorandum notes are intended "to improve the physical and mental health and general well-being of school going children".

The advent of the COVID-19 pandemic has posed new challenges to mental health and well-being. A recent study on its impact on the workplace has found that almost half of respondents are at high risk of "pre-traumatic stress disorder" (pre-TSD), a condition described as "a syndrome involving involuntary intrusive images and flash forwards of haunting events that could be experienced during major disruptions such as COVID-19".[15] It appears that no statistics on the impact of pre-TSD were obtained regarding workers in the informal economy, or other sectors of society.

Bills in progress

Apart from the NHI Bill and the National Health Amendment Bill (Bill 29 of 2018)[16] (the Private Member's Bill which seeks to extend clinic hours), which were comprehensively analysed in the previous edition of the *Review*,[17] a number of Bills that impact directly or indirectly on persons with disabilities are currently at various stages of preparation or consideration.

Social Service Practitioners Draft Bill, 2019

The Minister of Social Development published a draft Social Service Practitioners Bill for comment in March 2020.[18] Although no explanatory memorandum has been placed on the Department's website as promised, the intent of the Draft Bill is clear. The Bill proposes to replace the existing Social Service Professions Act (Act 110 of 1978)[19] in its entirety. The existing Social Service Professions Council, its Professional Board for Social Work and Professional Board for Child and Youth Care, will all be replaced by the South African Council for Social Service Practitioners. The Council will operate through social service boards, including both professional boards and occupational boards, allowing for a far broader group of practitioners to be brought under regulatory control. In addition to the currently regulated professions, the following occupations will be regulated: early childhood development practitioners, community development practitioners, assistant community development practitioners, and caregivers. A caregiver is defined as "a registered social service practitioner who provides psychosocial and physical care and support to older persons, persons with disabilities and those with chronic illnesses". This is the sole reference to persons with disabilities in the Bill. Whereas the existing Act 110 of 1978 included 'one disabled person' in its Council,[20] no such provision is available in the present Bill. This a retrogression from the current position. New applicants for registration in a social service profession or occupation will be required to complete two years of remunerated community service. It remains to be seen whether this highly interventionist and far-reaching Bill will be considered feasible and implementable. In particular, it is unclear whether it will be possible for the large number of personnel engaged at the occupation level to complete formal training under the auspices of the Quality Council for Trades and Occupations (QCTO), even with recognition of prior learning. The intentions, though, are worthy of consideration.

Copyright Amendment Bill (Bill 13 of 2017)

This Bill has a highly significant impact on disabled persons. Almost four years since the entry into force of the Marrakesh Treaty[21] and almost two years after the National Assembly passed the Copyright Amendment Bill,[22] visually impaired persons are no closer to benefiting from the exceptions promised in these instruments. Such exceptions would enable persons with disabilities to make use of reading materials in accessible formats. Furthermore, the 'fair use' provision would provide lawful flexibility to educational institutions migrating to remote teaching and research, for example, with the closure of such institutions and subsequent limitation to contact teaching during the COVID-19 pandemic. The Bill was finally passed by both Houses of Parliament on 28 March 2019 and sent to the President for assent. In June 2020, a non-governmental organisation, Blind SA, approached the Constitutional Court to declare that the President had failed to fulfil his constitutional obligations.[23] The President subsequently took the alternative route provided in section 79(1) of the Constitution, by referring the Bill back to Parliament for reconsideration, citing reservations about the constitutionality of the Bill.[24] Such reservations are widely regarded as unfounded, and suggest that the President is bowing to pressure from multinational corporations and western trade lobbies opposed to the exceptions contained in the Bill.[25] The Bill has appeared on the parliamentary calendar of the Trade and Industry, and the Sports, Arts and Culture portfolio committees in August and September 2020, respectively.[26]

Cannabis for Private Purposes Bill, 2020

The previous edition of the *Review*[17] has reported the Constitutional Court judgment on the issue of cannabis use by an adult in private.[27] The court declared portions of the Drugs and Drug Trafficking Act (Act 140 of 1992)[28] and the Medicines and Related Substances Act (Act 101 of 1965)[29] to be constitutionally invalid, but allowed two years for Parliament to amend the legislation, with specific wording "read in" in the interim. Instead of amending the Medicines Act, the application of section 22A (9) to cannabis was avoided by rescheduling cannabis and specific cannabinoids from Schedule 7 to Schedules 6 (tetrahydrocannabinol) and 4 (cannabidiol). Amendments to the Schedules to the Drugs Act are being prepared by the Minister of Justice and Correctional Services. In addition, the Minister of Justice and Correctional Services has tabled the Cannabis for Private Purposes Bill in Parliament.[30] The Bill has been crafted within the confines of the Constitutional Court judgment, enabling an adult to possess, cultivate and use limited quantities of cannabis in private, only allowing an adult to obtain limited quantities or dried plants or cultivation material from another adult "without the exchange of remuneration". Harsh penalties, including custodial sentences of up to 15 years, are reserved for possession or cultivation of what are termed either "commercial" or "trafficable" quantities. Consumption of cannabis in a public place or in the presence of a child is also an offence. Critically, the Bill excludes anyone who is permitted or authorised to cultivate cannabis or deal in cannabis or cannabis products by any other Act of Parliament. That would include the provisions in the Medicines Act and Schedules allowing the production of medicinal cannabis, the cultivation of low-trans-delta-9-tetrahydrocannabinol (THC) cannabis for industrial purposes and the production

of cannabidiol (CBD)-containing complementary medicines.[a] However, the Bill would not protect those who cultivated larger quantities of cannabis for the preparation of oils or other extracts for medicinal purposes, unless licensed. The Bill also provides for the expungement of criminal records of all persons previously convicted for the possession or use of cannabis. However, given the constraints on parliamentary processes at present, the Bill is not expected to progress before the end of 2020.

A separate challenge to the Drugs and Drug Trafficking Act has recently been heard in the Johannesburg High Court.[31] At issue was the sentencing by a lower court of a number of children to "compulsory residence", a form of incarceration for juveniles in youth centres, for possession of cannabis. In question was whether criminal-type penalties should be imposed on children suspected of cannabis use when this was not the case for adults. The court conducted an extensive analysis of the constitutional issues and found that the committal of the children had breached a number of fundamental rights, in particular, sections: 9 (equality); 12 (freedom and security of the person); 28 (children); and 35 (arrested, detained and accused persons). The court also bemoaned the misapplication and misunderstanding of the Child Justice Act (Act 75 of 2008),[32] as the committal had fallen foul of the "best interests of the child" standard, in that the sentences applied a standardised order for all children regardless of their individual circumstances, as well as of a fundamental principle of the Child Justice Act that a child should not be treated more severely than an adult in the same circumstances. The court ordered that section 4(b) of the Drugs and Drug Trafficking Act was inconsistent with the Constitution and invalid to the extent that it criminalised cannabis use by children and that, pending reform of the law, no child should be arrested, prosecuted or diverted for contravening this provision. It also declared that section 53(2) read with section 53(3) of the Child Justice Act does not, under any circumstances, permit that a child who has committed the "offence" in question be placed in a diversion programme involving a period of temporary residence.

The previous edition of the *Review*[17] also reported on the judgment of the Western Cape High Court to the effect that section 63 of the Drugs and Drug Trafficking Act, which empowers the Minister of Justice and Correctional Services to amend the schedules to that Act, was unconstitutional, as it was an impermissible delegation of power and a breach of the separation of powers doctrine.[33] The case was argued before the Constitutional Court in February 2020, and judgment has been reserved.[34] The outcome of this case will have far-reaching implications for both the Drugs and Drug Trafficking Act and the Medicines and Related Substances Act, which both rely on the frequent amendment of their Schedules by the respective Ministers. Were such changes to be reserved for Parliament, this would hamper the ability to bring new medicines to market and control access thereto, to flexibly reschedule medicines in response to emerging safety data, as well as to efficiently respond to global changes in controlled substance regulation.

Medicinal cannabis has been used for the management of spasticity, which is a common feature of cerebral palsy.[35] Cannabidiol has been registered in other jurisdictions for the management of uncontrolled seizures in children, associated with Lennox-Gastaut and Dravet syndromes, as well as tuberous sclerosis complex.[36]

The much-anticipated National Drug Master Plan 2019-2024 was finally published in June 2020 by the Minister of Social Development, and includes very specific commitments to a harm-reduction approach.[37] The policy notes that "It is necessary to form relationships between the criminal justice and public health sectors, and to change laws and/or norms to support evidence-based harm reduction". The legislative reforms proposed here can be viewed as part of that effort. The process for re-appointment of the Central Drug Authority is also progressing.

Implementation of the National Health Act

Implementation of the National Health Act (Act 61 of 2003) and the provisions enabled by that legislation continue, albeit at a reduced pace. In May 2019, the Chief Executive Officer of the Office of Health Standards Compliance issued a Code of Conduct for Inspectors, as enabled by the Regulations issued in terms of the NHA.[38] Inspectors will be required to "promote transparency while respecting the right to confidentiality, through objectivity".

Of relevance to persons with disability, the Minister of Health designated a number of hospitals, in each province, to provide acute care, rehabilitation and palliative care for cerebral palsy patients at no cost, presumably relying on the NHA.[39]

Statutory health professions councils

Although no amendments to primary legislation are being considered at present, changes to regulations and rules continue to be developed and implemented. A brief account of the most important legislative instruments is provided.

Health Professions Council of South Africa (HPCSA)

Updating the scopes of practice of various categories of health professionals and the qualification on which

a THC and CBD are natural compounds found in plants in the *Cannabis* genus.

registration depends is an ongoing task. Draft amendments to the qualifications for various emergency personnel were published for comment,[40] while amendments were made to the specialities and sub-specialities in medicine and dentistry.[41] A draft scope of practice for nutritionists was published for comment,[42] but it was decided not to proceed with changes to the scope of practice of psychologists, previously published for comment.[43]

Disciplinary process is a key task for all statutory health professions councils, and the Minister updated minor elements of the regulations governing inquiries into alleged unprofessional conduct under the Health Professions Act (Act 56 of 1974).[44] Medical negligence has again featured in the decisions of the courts. An appeal by Dr van der Walt against his conviction for culpable homicide and sentence of five years' imprisonment has been set aside by the Constitutional Court (CC).[45] This conviction was based on his negligence in managing the care of a patient after she had given birth, resulting in her death. After unsuccessful appeals, van der Walt argued before the CC that his right to a fair trial enshrined in the Constitution, in particular his right as an accused person to adduce and challenge evidence, had been violated. Two of the three grounds he advanced were upheld by the court, namely, that the magistrate had made a ruling on the admissibility of certain evidence only at the time of handing down judgment; and that she had not relied on the evidence of the state's expert witness alone but augmented her information by reference to medical textbooks that the expert did not refer to in his evidence. As a result, van der Walt had been prejudiced in the conduct of his defence. The appeal was allowed not on the merits of the case, but because of the procedural irregularities, and the matter was referred back to the Director of Public Prosecutions for a decision on whether van der Walt should be charged and tried again. Medical negligence is a serious issue plaguing our health sector, and can result in disability or death.

Allied Health Professions Council of South Africa (AHPCSA)

The professions of aromatherapy and reflexology have now been brought within the regulatory ambit of the AHPCSA.[46] Proposed amendments to the Regulations issued in terms of the Allied Health Professions Act (Act 63 of 1982) were published for comment, dealing mostly with the registration of practitioners and students and the funds of the council.[47] The AHPCSA has also issued a series of board notices defining unprofessional conduct.[48,49] Such designations are critical to effectively protecting the public, and especially those who are vulnerable as a result of disabilities, chronic illness or advanced age.

South African Nursing Council (SANC)

A notice issued by the Minister of Health in June 2019, creating the categories of "enrolled nurse" and "general nurse" in terms of the Nursing Act (Act 33 of 2005) has caused much confusion.[50] Section 31 of the Act already creates the categories of professional nurse, midwife, staff nurse, auxiliary nurse and auxiliary midwife. The enrolled nurse category caters for a legacy cohort, as those currently on the rolls may continue to practice. All "legacy programmes" have ceased to admit new learners since 31 December 2019.[51] Nursing colleges are in the process of being designated as tertiary educational institutions.[52] The "general nurse" category will replace the staff nurse, and will be based on a three-year Diploma course. The confusion was evident in the draft regulations on the scope of practice of nurses and midwives, which were initially issued for the previous categories,[53] and then re-issued in terms of the new categories.[54] Although some progress has been made in defining the qualifications needed for specialist registration,[55] as required in section 56(1) of the Nursing Act, there is still no clarity on which specialist nurses will be permitted to prescribe medicines (in accordance with section 22A of the Medicines and Related Substances Act). In addition, no regulations have yet been issued to accompany section 56(6) of the Nursing Act, which enables the issuing of permits to nurses who constitute the largest number of prescribers (and dispensers) of medicines in primary health care clinics in the public sector. The SANC has published draft Rules to introduce compulsory continuing professional development (CPD) for nurses, based on accredited providers and a points system.[56]

South African Pharmacy Council (SAPC)

The SAPC has also introduced compulsory CPD as a requirement for ongoing registration as a pharmacist designated to be practising.[57] The system relies on the maintenance of a portfolio of evidence and the electronic submission of a prescribed number of CPD activities, using a cycle of reflection on practice, planning, implementation and evaluation by pharmacists of the progress made towards achieving their learning objectives. Minor updates to Good Pharmacy Practice (GPP) standards have been issued,[58] but more importantly, guidelines have been issued for the removal of pharmacy from registration/recording as a result of non-compliance with GPP or other legislation.[59] The Minister of Health has also issued draft regulations to introduce a new category of pharmacy technician, with two possible routes of education and training (an occupational and a higher education route).[60,61] The SAPC has accordingly issued Good Pharmacy Education Standards for the Occupational Qualification Sub-Framework.[62]

The provisions of section 22A of the Pharmacy Act (Act 53 of 1974)[63], read with Regulation 6 of the Practice Regulations issued in terms of that Act, came under scrutiny in the case of Independent Community Pharmacy Association v Minister of Health and Others.[64] Section 22A enables the Minister of Health to prescribe who may own a pharmacy and the conditions under which such persons may do so, as well as the conditions under which such authority may be withdrawn. The court was required to interpret the import of the prohibition in Regulation 6 to the effect that an entity that has a beneficial interest in a community pharmacy is barred from being the holder of a direct or

indirect beneficial interest in a manufacturing pharmacy. The court found the concept of 'beneficial interest' to be of wide import: without owning the assets of a company, a shareholder has a beneficial interest in the operations and profits of the company's business. As such, the court found that there was a conflict of interest as envisaged by the legislation between New Clicks' role as a retail pharmacy chain, and as the owner of Unicorn, the manufacturing pharmacy. As a result, New Clicks stood to gain financially to the prejudice of consumers who would be prompted to purchase the product manufactured by Unicorn, and thus potentially not receive the best quality product at the best price. The court ordered that the sanction to be imposed for the contraventions be remitted to the Chairperson of the Appeal Committee, or alternatively to the Director-General of Health where the matter was first heard, for consideration. This is an ongoing issue, so the longer-term implications have yet to be uncovered. The decision is an important test case for the prohibition of vertical integration in the private healthcare market.

South African Health Products Regulatory Authority (SAHPRA)

SAHPRA has been key to a variety of responses to the COVID-19 pandemic, not least in terms of the nascent regulation of medical devices and *in vitro* diagnostics (IVDs). For example, on the recommendation of SAHPRA, the Minister of Health has excluded the manufacturers of certain alcohol-based hand-rubs from the requirement for licensure and labelling, on certain conditions.[65] Extension to the period of validity of repeat prescriptions for Schedule 2 to 4 medicines was also enabled, for a time-limited period.[66] Two further Gazette notices are indicative of the ongoing process of transformation from the Medicines Control Council (MCC) to SAHPRA. The first relates to the referral, in October 2019, to the Special Investigating Unit (SIU) of allegations of maladministration, improper or unlawful conduct, or corrupt activities at SAHPRA.[67] No further information on progress with this investigation has been forthcoming. The second relates to the fees charged by SAHPRA. In 2008, the Green-Thompson report noted that the fees charged for registration applications by the MCC were low compared with fees in other countries.[68] The proposed fee for a new medicines application was R165 200. More than a decade later, the new proposed fee for a similar application is in the range of R111 000 (new chemical entity, abbreviated registration process) to R208 400 (new biological medicine, other than vaccines).[69] SAHPRA will be required to take urgent and at times difficult decisions about clinical trials for COVID-19, including for vaccines. The Authority will also need to decide on the registration of medicines and vaccines for COVID-19, on the basis of incomplete evidence. Nominations were invited, by 3 July 2020, for appointment to the SAHPRA board.[70]

On 1 October 2020, the North Gauteng High Court ruled on a challenge to the regulatory framework for complementary medicines, including health supplements.[71] The court's finding, namely that the 2017 General Regulations issued by the Minister of Health were unlawful to the extent that they applied to complementary medicines and health supplements that are not medicines or scheduled substances, is being appealed by the respondents.[72]

Although the annual determination of the single exit price adjustment[73] and dispensing fees for pharmacists[74] and licensed dispensing practitioners[75] has continued, application of the pricing provisions in the Medicines and Related Substances Act will still not apply to medical devices and IVDs, as these were excluded for a further three years from May 2019.[76] In addition, in May 2020, the Minister of Health excluded all medicines, medical devices and IVDs donated to the State, or provided as a sample during a tender process, from the ban on sampling in terms of section 18B, again for a period of three years.[77] Although catered for in the Medicines and Related Substances Act, the pricing provisions fall outside of the remit of SAHPRA. Nominations were also invited, by 12 August 2020, for appointment to the Pricing Committee.[78]

Specific Disaster provisions

Apart from the exclusion notices issued in terms of section 36 of the Medicines and Related Substances Act, a plethora of regulatory notices have been issued pursuant to the declaration of a State of Disaster in March 2020.[79] An example is the amendment to regulations on the handling of human remains, in terms of the NHA.[80] These amendments, for example, prohibited the viewing and storage of the body of a COVID-19 victim at home. The Minister of Trade and Industry has also exempted manufacturers and suppliers of "medical and hygiene supplies" from specific prohibitions on collusive behaviour, provided it is for the sole purpose of communicating on availability and co-ordinating procurement and distribution.[81]

Conclusion

In many ways, 2020 has been a year 'on hold', with specific major health-related legislative processes delayed or in abeyance. The year has, nonetheless, provided an important test of existing legal provisions and their resilience. Viewed from the perspective of persons with disabilities, much of the existing legislation appears to pay little more than lip-service to South Africa's international obligations and the fine promises entrenched in the Constitution and the National Health Act. In particular, if the resources required to ensure the integration of services signalled in the Framework and Strategy for Disability and Rehabilitation Services in South Africa 2015-2020 are to be mobilised and equitably applied, they need to be explicitly referenced in the benefit package to be delivered under National Health Insurance.

The relative marginalisation of persons with disabilities appears to be a global problem. This is reflected to some extent in the WHO's Comprehensive Global Monitoring Framework,[82] which proposed a list of indicators for the prevention and control of four major diseases. The framework has been criticised for not adequately addressing disability.[83]

"Equity in health is an ethical value, inherently normative, grounded in the ethical principle of distributive justice and consonant with human rights principles".[1] Regrettably, the slow progress with regard to equity in health for disabled persons recounted here is a sad commentary on the failure of both distributive justice and protection of the human rights of such persons.

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