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HCJ 4013/05 Gila Louzon v. Government of Isrel 1

HCJ 3071/05

- 1. Gila Louzon
- 2. Adolf Edri
- 3. "Last Border" Amuta for Cancer Patients
- v.
- 1. Government of Israel
- 2. Minister of Health
- **3.** Minister of Finance
- 4. Committee for Expanding the Medicinal Services Basket appointed by the Council for National Health Insurance

HCJ

3938/05

- 1. Yaakov Bar-On
- 2. Uriel Gilon
- 3. Zion Halifi
- 4. Eliyahu Yitah
- 5. Emile Huri
- 6. Keren David
- 7. Asher Miara
- 8. Shlomo Ginosar
- v.
- 1. Ministry of Health
- 2. Minister of Health
- 3. Ministry of Finance
- 4. Minister of Finance

HCJ 4013/05

- 1. Yaakov Sheiber
- 2. Haim Edelstein
- 3. Shlomi Segal
- 4. Hayat Yosepov
- v.
- 1. State of Israel
- 2. Minister of Health
- **3.** Minister of Finance
- 4. Industry and Trade Minister
- 5. Supervisor of Prices and the Committee under the Price Supervision Law
- 6. Committee for Expanding the Medicinal Services Basket appointed by the Council for National Health Insurance
- 7. General Health services
- 8. Macabbi Health services
- 9. Meuchedet Health Fund
- 10. Leumit Health Fund

The Supreme Court sitting as the High Court of Justice (8 August 2005)

Before President D. Beinisch and Justices A. Grunis, M. Naor

Petition to the Supreme Court for sitting as the High Court of JusticeOrder *Nisi* and an interim order

**Facts:** The petitioners had difficulty in purchasing the medications not included in the health basket independently, and therefore petitioned the Supreme Court requesting it to instruct the respondents to include their medications in the publicly-funded health services basket. The petitioners argued that the decision to omit these medications from the health services basket approved for 2005 violated their constitutional rights,

insofar as their right to life includes the right to health, and by extension, the right to receive publically funded medical/medicinal treatment, as a derivative of the right to life and bodily integrity and human dignity, all in a manner that was contrary to the conditions of the limitations clause, and which discriminated against them adversely vis-à-vis other patients whose required medications were included in the basket. Secondly the petitioners challenged the manner in which the Committee exercised its discretion in deciding which medicines warrant inclusion in the publically funded health basket, and that in its prioritization of new medical technologies it overrated the budgetary consideration, which translated into a relatively low ranking for life-saving or life-prolonging medications, and failed to ascribe the requisite importance to the value of saving human life.

The State argued that the matter at hand necessitated judicial restraint and that in the present context the court should refrain from deriving a general constitutional right to health and medical care from the framework rights anchored in Basic Law: Human Dignity and Liberty.

The State argued that prioritization of ranking new medications and technologies was a complex decision, involving a broad spectrum of considerations, and that it was subject to the budgetary restrictions that were set in accordance with the Government's overall scale of priorities, given that Erbitux, is a new medication, and its effectiveness in improving the symptoms of colon cancer patients or prolongs their lives is unknown. As such the Committee was entitled to give it a lower priority than other medications that had been proven to be life-prolonging. Inasmuch as the recommendation was adopted after a thorough, informed, and in-depth decisionmaking process, legally conducted, there are no grounds for interfering with it.

**Held:** In determining the constitutionality of the right to health as a derivative of the constitutionally protected right to life, the right cannot be examined as one composite whole but rather, the rationales for the various rights and interests protected in its framework should be considered in accordance with their relative social importance and with the strength of their connection to the constitutional rights enumerated in the Basic Law. The constitutional right to life in the Basic law is likely to include aspects from the areas of welfare and social security, including health care and health services. In defining the right to health services a distinction can be made between "basic health services" necessary for maintenance of decent human existence, and services which are beyond the basic level for human existence in society, such as right to receive

publically funded health care, which is an affirmative expression of the right to health, imposing a duty upon the state for public funding of health services. The right to publically funded health services, like other socio-economic rights has a dominantly positive character, and the court is wary of intervening in the formulation of overall economic policy, absent an explicit anchoring of social rights in legislation. These factors make it doubtful whether the demand for public funding for these innovative medications is part of the hard kernel of constitutional rights enumerated in the Basic Law. Furthermore, even according to an interpretative approach that extends the constitutional scope of the right to human dignity beyond the level of the basic minimum in the area of welfare and social security, it would appear that only in extreme and exceptional circumstances would the state be constitutionally obligated to fund a specific medication, one of many in respect of which applications are submitted for public funding. As such it would seem that it has not been proved that a constitutional right of the petitioner was violated.

The scope of the State's responsibility to ensure the access to and provision and funding of health services in Israel is set forth in the legal system, in various pieces of legislation, independently of its constitutional status. The arrangements in the Patient's Rights Law and in the National Insurance Law indicate two basic principles. Firstly, that the basket of health services does not purport to cover all of the possible medical services of the scope and level that each individual patient may require. Secondly, the Israeli legal system confers a legal right to public health services of a broader scope than bare minimum of health services required for human existence in a society.; The legal right to public health services may be viewed in terms of a core and a periphery. The core of the legal right to public health services includes all the public health services that the state is obligated to fund. The periphery includes all of the other health services that are not included in basic basket of health services, and which are therefore "budget dependent". As such the scope of the right to public health services which are in excess of the basic basket is a function of the Annual Budget Law. The Basket Committee is part of the public administration, governed by administrative law and subject to judicial review on that basis. Nothing in the manner of its operation indicated a defect that could justify judicial intervention It is authorized to determine the contents of the health services basket and to advise the relevant bodies regarding the determination of priorities regarding new technologies for purposes of widening the health basket. In doing so the budgetary consideration is a legitimate one and there is similarly no defect in distinctions such as effectiveness of the medication in the treatment of sickness and the question of whether there was proven capacity to

prolong life. Distinctions of this kind do not constitute unlawful discrimination for as long as they are based on relevant and reasonable criteria,

*Justice Naor*: There are two categories of decisions in public administration: those involving confrontation between dual-focus problems, admitting of a yes or no answer, and hence classically suited to judicial review, and multi-focal problems, in which there are no yes or no answers, and which do not readily admit of a balancing formula. Problems of this nature are more suited to administrative authority,

The decision not to include the desired medication in the basket, on the basis of the extant information relating to it, does not exceed the bounds of reasonability, and there were no grounds for interfering with it.

The petition was therefore denied.

# Legislation Cited

Patient's Rights Law, 5756-1996, s. 3. Do Not Stand on Your Neighbor's Blood Law, 5758-1998 National Health Insurance Law, 5755-1995 Value Added Tax Law, 5736-1976

### Israel Supreme Court cases cited:

- [1] HCJ 6055/95 Tzemach v. Minister of Defense (1999) IsrSC 53(5) 241; [1998-9] IsrLR 635
- [2] HCJ 4128/02 Man, Nature and Law Israeli Society for the Protection of the Environment v. Prime Minister of Israel (2004) IsrSC 58(3) 503.
- [3] HCJ 494/03 Physicians for Human Rights v. Minister of Finance (2004) IsrSC 59(3) 322, [2002-2003] IsrLR 35..
- [4] LCA 4905/08 Gamzo v. Isaiah [2001] IsrSC 58(3) 360.
- [5] HCJ 5578/02 Manor v. Minister of Finance (2004) IsrSC 59(1) 729.
- [6] HCJ 2557/05 Mateh Harov v. Israel Police (2006) (unreported).
- [7] HCJ 4769/95 Menahem v. Minister of Transport [2002] IsrSC 57(1) 235.
- [8] HCJ 366/03 Commitment to Peace and Social Justice Society v. Minister of the Interior (2005) (unreported) [2005] (2) 335.
- [9] HCJ 2599/00 Yated v. Ministry of Education (1999) IsrSC 56(5) 834., [2002-2003] IsrLR 57.
- [10] HCJ 7351/03 Rishon Le-Zion Municipal Parents Committee v. Minister of Education, Culture and Sport (2005) (unreported) 2005] (2) IsrLR 1.

- [11] CA 5557/95 Sahar Insurance Company Ltd. v. Alharar (1997) IsrSC 51(2) 724.
- [12] HCJ 2344/98 Macabbi Health Services v. Minister of Finance [2000] IsrSC 54(5) 729.
- [13] HCJ 9163/01 General Health Services v. Minister of Finance [(2002] IsrSC 55(5) 521.
- [14] HCJ 1554/95 Supporters of Gilat Amuta v. Minister of Education, Culture and Sport [1996] IsrSC 50(3) 2.
- [15] HCJ 2725/92 General Health Services v. State of Israel [2004] IsrSC 59(1) 781.
- [16] HCJ 1829/02 General Health Services v. Minister of Health [2003] IsrSC 58(1) 406.
- [17] HCJ 7365/95 Bolous Brothers Marble and Granite Production Ltd v. Investments Centre [1996] IsrSC 50(2) 89.
- [18] HCJ 3472/92 Brand v. Minister of Communications [1993] IsrSC 47(3) 143.
- [19] HCJ 3627/92 Israel Fruit Growers Organization Ltd. v. Government of Israel [1993] IsrSC 47(3) 387.
- [20] HCJ 2453/06 *Israeli Medical Association v. Attorney General* (2006) (not yet reported).
- [21] HCJ 4004/07 (2007) (not yet reported).
- [23] HCJ 4613/03 Shaham v. Ministry of Health [2004] IsrSC 56(6) 385.
- [24] HCJ 1113/99 Adallah v. Minister for Religious Affairs (2000) (unreported).
- [25] HCJ 2974/06 Israeli v. Committee for Expanding the Health Services Basket (2006) (not yet reported).
- [26] HCJ 3997/01 Neopharm Ltd. v. Minister of Finance (2001) (unreported).
- [27] HCJ 7721/96 Israeli Insurance Assessors Association v. Inspector of Insurance [2001] IsrSC 55(3) 625.
- [28] HCJ 82/02 Kaplan v. State of Israel, Ministry of Finance, Customs Division [2004] IsrSC 58(5) 901.
- [29] CA 8797 Anderman v.Objection Committee of District Committee under the Planning and Construction Law, 5725-1965, Haifa [2001] IsrSC 56(2) 466.
- [30] HCJ 10/00 Raanana Municipality v. Inspector of Transport, Tel-Aviv and Central Districts [2001] IsrSC 56(1) 739.
- [31] CCT 8/02 Minister of Health v. Treatment Action Campaign [2002] (10) BCLR 1033.
- [32] CCT 32/97 Soobramoney v. Minister of Health [1997] (12) BCLR 1696.

For the petitioners in HCJ 3071/05 – Orna Lin, Michal Shtein For the petitioners in HCJ 3938/05 – Gideon Korn, Sigal Zept For the petiioners in HCJ 4013/05 – David Sasson, Uri Shiber For the respondents in HCJ 3071/05 and HCJ 3938/05 – Einat Golomb For the respondents 1-6 in HCJ 4013/05 – Dana Briskman For respondent 7 in HCJ 4013/05 – Arial Meitlis For respondent 8 in HCJ 4013/05 – Azga Shtern, Naama Elad For respondent 9 in HCJ 4013/05 – Shira Hana Melamed, Momi Dahn For respondent 10 in HCJ 4013/05 – Omer Eshkar

# JUDGMENT

The petitioners in these three petitions suffer from various forms of cancer. The petitioners' doctors referred them for medicinal treatment, and when these petitions were filed, the petitioners' required medications were not included in the basket of health services that receives public funding under the provisions of the National Health Insurance Law, 5754-1994 (hereinafter: "National Health Insurance Law"). The petitioners had difficulty in purchasing the medications independently, and this was the basis for their petition to this Court requesting that we instruct the respondents to include their medications in the publicly-funded health services basket (hereinafter: "the basket" or "the health services basket"). The petitioners argue that the decision to omit these medications from the health services basket approved for 2005 violated their constitutional rights, it was unreasonable, and it discriminated against them adversely vis-à-vis other patients whose required medications were included in the basket.

As will be clarified below, Government Decision no. 406 concerning a budgetary supplement to the health services basket was adopted on 27 August 2006. Following the budgetary supplement, the medications constituting the subject of the petitions in HCJ 3071/05 (hereinafter: HCJ *Louzon*) and HCJ 3938/05 (hereinafter: HCJ *Bar-On*) were included in the basket. On the other hand, the medication discussed in petition HCJ 4013/03 (hereinafter: HCJ *Sheiber*) was not included in the basket, and remains for our consideration.

### The factual background preceding the filing of the petitions

1. The health services basket as defined in s. 7 of the National Health Insurance Law includes the health services that all Israeli residents insured under the Law are entitled to receive from the sick funds, by means of funding sources that are the responsibility of the State. Below we will discuss the arrangements prescribed by the National Health Insurance Law and the means for determining the contents of the health services basket. At this stage we note that in 2005, when the current petitions were filed, the Ministry of Health had received requests for the addition of about 400 new medicines and technologies to the health services basket. These requests, together with the professional literature and the processed data pertaining to each request, were submitted to the Public Committee for the Expansion of the Health Services Basket (hereinafter: the Committee.) The Committee held a number of

meetings, following which it prioritized the medications in an order that was influenced, *inter alia*, by the Committee's assessment of the urgency of the various medications.

The Committee's recommendations were presented to the Government on 21 March 2005 in the framework of a debate on the budget for the addition of new technologies to the health services basket. On 13 April 2005 the Government passed a decision approving the addition to the basket of the medications and technologies listed in a table appended to its decision. This decision also determined that "...the cost of the 2005 health services basket will express the addition of technologies at an annual cost of NIS 350 million in accordance with the prices of the average health cost index of 2004...." The budgetary supplement made possible the addition to the health services basket of some of the medications recommended by the Committee. Nevertheless, certain medications for various forms of cancer were excluded from the health services basket, not having been accorded sufficient priority by the Committee. This was the background to the filing of the three petitions to this Court.

# The course of events in the three petitions

2. The petition in HCJ *Louzon* was filed by patients suffering from cancer of the colon, and by an *amuta* [non-profit organization] established for the purpose of helping them. According to the petition, doctors who treated the petitioners had referred them for treatment with Avastin, but as this medication was not included in the health services basket, the petitioners were forced to purchase it independently. The medication was particularly expensive, and the petitioners were unable to continue financing it. They therefore petitioned this Court, requesting it to instruct the respondents to include Avastin in the health services basket, in the category of treatment for colon cancer.

The petition in HCJ *Bar-On* was filed by several petitioners suffering from prostate cancer that had progressed to the metastatic stage, which is resistant to hormonal treatment. Their doctors recommended Taxotere; this medication, too, was excluded from the 2005 health services basket. Against this background, the petition was filed asking the Court instruct the respondents to include Taxotere in the requested category, along with other remedies.

The four petitioners in HCJ *Sheiber* were suffering from colon cancer and needed Erbitux, a medication which was similarly excluded from the health services basket of 2005. Owing to the high cost of the medication, this Court was requested to order that Erbitux be included in the health services basket in the category of treatment for colon cancer; the petitioners also sought additional remedies, which we will discuss below.

3. Soon after the petitions were filed, they were scheduled for an early hearing. On 4 April 2005 the petition in HCJ *Louzon* was heard by President A. Barak and Justices A. Procaccia and M. Naor. That session concluded with the Court deciding to grant the order *nisi* sought in the petition. On 24 May 2005 the petitions in HCJ *Bar-On* and HCJ *Sheiber* were heard by Justices E. Rivlin, E. Rubinstein and S. Joubran, and at the end of the hearing the Court decided to grant the request of the petitioners in HCJ *Bar-On* to file an amended petition. The Court further decided to grant an order *nisi* regarding some of the remedies sought in HCJ *Sheiber*.

After the amended petition was filed and responded to in HCJ *Bar-On*, and after the filing of responding depositions in the other petitions, all three petitions were scheduled for hearing on 8 August 2005 before this panel (President D. Beinisch, Justices A. Grunis and M. Naor). At that time, the issue of funding the basket surfaced on the public agenda, and a public campaign was waged to increase the budget so as to enable the inclusion of new technologies in the basket. We deemed it appropriate to defer our judgment, pending the possibility of the petitions being resolved without the need for this Court's intervention.

Indeed, in the State's update to this Court, it stated that on 9 April 2006 the Israeli Government decided to expand the health services basket by including new technologies, thus adding the sum of NIS 165 million to the 2006 basket. At this stage it became clear that the medications forming the subject of these petitions were not included in the budgetary supplement decided upon by the Government. A second update submitted by the State a few months later stated that the Government had decided upon an additional expansion of the health services basket by including new technologies to the 2007 budget, at an annual yearly cost of NIS 237.28 million, which would be brought forward to the 2006 budget (Government decision No. 406). As a result of this decision, as of 20 September 2006, Avestin was added to the category of first-line

treatment for metastatic colon cancer which was the subject of the first petition in HCJ *Louzon*. In addition, the Taxotere medication was also labeled as a first-line treatment of metastatic prostate cancer which was resistant to hormonal treatment – the subject of the HCJ *Bar-On*.

As noted earlier, the Erbitux medication constituting the subject of the *Sheiber* petition was not ranked highly enough by the Committee, and even after the budgetary supplement for the year 2006, it was excluded from the health services basket. The Government subsequently decided to increase the budgetary funding for the 2008 health services basket: initially a supplement of NIS 380 million was approved and finally an overall sum of NIS 450 million was approved. Even after the budgetary supplement, however, the Erbitux medication in the category of colon cancer remained outside the basket.

### HCJ Bar-On and HCJ Louzon

4. As mentioned, following the budgetary supplement that expanded the 2006 health services basket, Avestin and Taxotere were added to the requested categories in the 2006 health services basket. This meant that a practical solution was found for the main remedy requested in HCJ *Louzon* and HCJ *Bar-On*, even though unfortunately, this was only after most of the petitioners had already passed away.

On 27 September 2006, counsel for the petitioners in HCJ *Bar-On*, Adv. Sigal Zeft, informed us that since Taxotere had been included in the health services basket, the petitioners were waiving further hearing of their petition. As for HCJ *Louzon*, counsel for the petitioners, Advs. Orna Lin and Michal Stein, informed us on 3 October 2006 that despite the inclusion of Avestin in the category of metastatic colon cancer in the 2006 health services basket, they still felt their petition should be heard. In their view, the inclusion of Avestin in the health services basket did not obviate the fundamental arguments raised in the petition against the Committee's mode of operation and the manner in which it exercised its discretion, and a decision should be made on these arguments. Regarding this assertion, it must be said that in general, this Court will not rule on a petition that previously related to an actual issue but has, in the circumstances, become superfluous. The High Court of Justice has already ruled that "...if the case constituting the subject of a petition is resolved, by itself or by judicial decision, the Court will no longer be prepared to consider

the legal question it raises" (HCJ 6055/95 *Tzemach v. Minister of Defense* [1], *per* Justice I. Zamir, at para. 3). It is not disputed that as of 2006, there has been a solution for the remedy sought in HCJ *Louzon* regarding the inclusion of Avestin in the health services basket. This being the case, we see no need to rule on the series of questions raised in that petition. All the same, it is noteworthy that some of the questions raised by counsel for the petitioners in HCJ *Louzon* concerning the violation of the petitioners' constitutional rights and concerning the manner in which the Committee exercised its discretion were also raised by the petitioners in HCJ *Sheiber*. These issues will be discussed below.

Therefore, and in view of the inclusion of Avestin and Taxotere in the requested categories of the 2006 health services basket, the order *nisi* granted in the *Louzon* case will be cancelled and the petitions in HCJ *Louzon* and HCJ *Bar-On* will be withdrawn with no order for costs. The petition in HCJ *Sheiber* therefore remains for our decision.

# HCJ Sheiber – the pleadings of the parties

5. Two main remedies were requested by counsel for the petitioners, Adv. David Sasson, in HCJ *Sheiber. First*, this Court was requested to order the addition of Erbitux, in the category for treatment of colon cancer, to the list of approved medications in the health services basket. *Secondly*, the petitioners requested an order that action be taken in one or more of the ways specified in the petition, with the aim of reducing the price that cancer patients are required to pay for medications not included in the health services basket.

In their petition, the petitioners raised several main arguments. *First*, it was argued that the right to health is part of the right to life and bodily integrity, and the right to human dignity, which are anchored in Basic Law: Human Dignity and Liberty (hereinafter: "the Basic Law"). The claim is that the non-inclusion of the Erbitux medication unlawfully violated the petitioners' constitutional rights, contrary to the conditions of the reservations clause. *Secondly*, the petitioners challenged the way in which the Committee exercised its discretion. In this context, they stressed that they were not challenging the budgetary framework determined by the Government for funding the basket should be based on a format that provided equal funding for all life-saving or life-prolonging drugs, without preferring any

particular medication at the expense of another. In this context, it was further asserted that by not including Erbitux in the health services basket, appropriate weight was not assigned to the value of saving human life, and this constituted discrimination against the petitioners in relation to other patients whose required medications were included in the basket.

A significant part of the petitioners' claims turned on their proposals for reducing the cost of medications *not* included in the health services basket, in order to help patients in financing the purchase of these medications independently. In this context, the petitioners proposed a number of solutions, including: cancellation of value added tax and other indirect taxes levied on the sale of life-saving medications; the centralized purchase by the Ministry of Health and/or the Sick Funds of life-saving drugs not included in the health services basket, in a manner that would reduce the prices for those patients who required them.

6. Counsel for the State, Adv. Dana Briskman and Adv. Einav Golomb, whose responses were comprehensive and erudite, argued that the HCJ *Sheiber* petition should be denied. Regarding the petitioners' claim concerning the unlawful violation of their constitutional rights, counsel for the State referred to the responding deposition filed in HCJ *Louzon*. According to the State, in the matter at hand, this Court should exercise judicial restraint and the utmost caution in the present context, and refrain from deriving a general constitutional right to health and medical care from the framework rights anchored in Basic Law: Human Dignity and Liberty.

As to the petitioners' arguments concerning the manner in which the Committee exercised its discretion, the State responded that a decision on ranking new medications and technologies was a complex one, involving a broad spectrum of considerations, and that it was subject to the budgetary restrictions that were set in accordance with the Government's overall scale of priorities. Erbitux, it was argued, is a new medication, and it is not yet known whether it improves the symptoms of colon cancer patients or prolongs their lives. Bearing this in mind, the Committee deemed that it could not be given higher priority than other medications which had been proven to be lifeprolonging. The argument is therefore that the recommendation was adopted after a thorough, informed, and in-depth decision-making process, which was

conducted in accordance with the law; as such there are no grounds for interfering with it.

With respect to the petitioners' proposals to reduce the price of medications not included in the health services basket, it was argued that these proposals should be rejected *in limine* in view of the failure to exhaust all alternative avenues and to apply initially to the relevant authorities. The State addressed the various proposals on their substance, and presented its reasons for rejecting the petition as it related to them.

7. The four Sick Funds in Israel are also respondents to the petition. In their responses, they argued that they are not relevant respondents to the petitioners' request to include Erbitux in the health services basket, since under the provisions of the National Health Insurance Law, it is not the Sick Funds that determine the contents of the basket, and their role consists exclusively of the provision of the services included therein. Regarding the petitioners' proposal for the Sick Funds to carry out a centralized purchase of the medications not included in the health services basket in order to reduce the price for their members – it was argued that the National Health Insurance Law does not obligate the Sick Funds to carry out a centralized purchase. Nevertheless, some of the Sick Funds indicated in their response that they would not oppose a centralized purchase of medications not included in the health services basket, but their consent was contingent upon the prior regulation of all aspects and questions involved in the matter.

8. The petition in HCJ *Sheiber* therefore raises various issues pertaining to the health services basket in Israel. Our discussion of these questions will proceed as follows: first, we will consider the petitioners' argument that non-inclusion of Erbitux in the health services basket unlawfully violates their constitutional rights. We will then discuss the petitioners' objections to the manner in which the Committee exercised its discretion in determining the contents of the health services basket. Finally, we will address the petitioners' various proposals for reducing the prices of the medications not included in the basket.

### The constitutional status of the right to health

9. The petitioners asserted that the Committee ranked the new medications and technologies in a manner that violated their constitutional right to health, thereby contravening the conditions of the reservations clause.

The petitioners conceded that the right to health is not explicitly prescribed in the basic legislation, but claimed that it derives from the right to life and bodily integrity as well as from the right to human dignity, both of which are anchored in Basic Law: Human Dignity and Liberty.

In addressing these arguments of the petitioners, we will note at the outset the difficulty involved in defining the internal scope of the right to health, since *prima facie* it covers an exceedingly broad domain. In principle, the right to health can be viewed as a collective term for a cluster of rights related to human health, some of which enjoy constitutional status in our legal system. For example, the right to health includes the right to preservation of the patient's privacy and protection of his autonomy by disclosure of all medical information concerning him and obtaining his consent to any treatment administered to him. The right to health likewise includes the right not to be discriminated against with respect to access to medical treatment. It also includes additional aspects that affect people's health, such as public awareness and access to information on health-related matters, access to acceptable food and drinking water in suitable sanitary and environmental conditions that are not harmful to human health, and other matters as well (see: Committee on Economic, Social and Cultural Rights, General Comment 14, The Right to the Highest Attainable Standard of Health, U.N. Doc. E/C.12/2000/4, at www.unhchr.ch/tbs/doc.nsf/(symbol)/E.C.12.2000.4.En (hereinafter: General Comment 14 of the U.N. Committee on Economic, Social and Cultural Rights). Considering the many aspects of the right to health, there would seem to be no basis for examining the constitutional status of the right as one composite whole; rather, the rationales for the various rights and interests protected in its framework should be considered, in accordance with their relative social importance and with the strength of their connection to the constitutional rights enumerated in Basic Law: Human Dignity and Liberty (see and compare: Justice D. Dorner on the "right to a decent environment" in Man, Nature and Law v. Prime Minister [2], para. 2).

10. This petition is concerned with the right to health-care, and more precisely with the right to receive publicly funded medical/medicinal treatment. Inarguably, the right to medical treatment is not explicitly mentioned in the framework of the basic laws concerning human rights. As is known, the attempts to enact basic legislation that would confer explicit

constitutional status on social rights, including the right to health and medical treatment, have thus far failed (see e.g.: Draft Basic Law: Social Rights, HH 5754, 337; see also the proposal of Law and Constitution Committee, "Broadly-Accepted Constitution", ss. 17, 18A - <u>www.knesset.gov.il/HUKA</u>; see further and cf: "Constitution by Agreement", Proposal of the Israeli Democracy Institute, ss. 32, 34 - <u>www.e-q-m.com/clients/Huka/huka\_01.htm</u>. Taking this into consideration, the question of the degree to which the right to medical treatment enjoys constitutional status in our legal system is far from simple. This is especially the case in relation to the "affirmative" aspect of the right, which imposes upon the state a positive duty to act, the essence of which is responsibility for the public funding of health services in Israel. One of the central dilemmas in this context would appear to lie in the definition of the internal-constitutional scope of the right to medical treatment in general, and the right to publicly-funded health services in particular.

This Court has already ruled that the right to inclusion in the national health insurance system, per se, does not enjoy constitutional meta-legal status (see HCJ 494/03 Society of Physicians for Human Rights v. Minister of Finance [3] (hereinafter: Physicians for Human Rights v. Minister of Finance), para. 18). Alongside the aforementioned ruling, the view has been expressed in our case-law that "a person without access to elementary medical treatment is a person whose human dignity has been violated" (per President A. Barak in LCA 4905/08 Gumzo v. Isaiah [4], para. 20). It has also been determined that "... the social right to the provision of basic health services can be anchored in the right to bodily integrity under s. 4 of the Basic Law" (per President A. Barak in Physicians for Human Rights v. Minister of Finance [3], paras. 16, 18; emphasis added - D.B.). Furthermore, the view was expressed that the right to medical treatment in a medical emergency involving immediate physical distress, being a right grounded in s. 3(b) of the Patient's Rights Law, 5756-1996, may be included in the category of protected rights in the framework of Basic Law: Human Dignity and Liberty (ibid, para. 18).

Thus, it emerges from the case-law of this Court that the constitutional rights enumerated in Basic Law: Human Dignity and Liberty are likely to include various aspects from the areas of welfare and social security, including health care. However, our case-law has yet to consider directly the question of

which "basic health services" are included within the parameters of the constitutional rights enumerated in the Basic Law, and whether a constitutional right to health services that extends beyond the basic level required for human existence in society should be read into these constitutional rights. This dilemma is reflected in the pleadings of the parties in the case before us. On the one hand, the centrality of health to the maintenance of decent human existence, to the welfare of the individual and to his ability to realize all other human rights is undisputed. Where medicinal treatment with any particular potential for saving, prolonging or improving the patient's quality of life is concerned, significant weight should be assigned to the value of the sanctity of life, the integrity of body and soul, and human dignity, all of which are central values with constitutional standing in our legal system. Regarding the receipt of publicly-funded medical treatment, the legislation of the State of Israel is characterized by a commitment to a public health system grounded in the principle of mutual responsibility and concern for the society's indigent, as indicated by the provisions of the National Health Insurance Law, which we will address below.

On the other hand, as mentioned above, the right to public health services in the present context means imposing a positive duty on the state, the main substance of which is responsibility for public funding of medical-medicinal treatment. Naturally, the issue of the constitutional scope of that right involves general distributive questions that derive from the nature of the socioeconomic regime governing a society and the scope of public resources at the state's disposal (cf: HCJ 5578/02 Manor v. Minister of Finance [5], para. 9, per President A. Barak). Indeed, the human rights recognized in our system, which are generally referred to as "civil and political rights", also impose upon the State "positive" duties of protecting the realization of a right, and not just "negative duties" of not violating the right. Quite often the state's duty to protect the realization of civil and political rights also includes a "positive" duty that involves the allocation of substantial resources (see e.g. in the context of freedom of speech and demonstration: HCJ 2557/05 Mateh Harov v. Israel Police [6], per President A. Barak, at para. 14 ff.). Even so, it seems that the right to publicly funded health services, like other rights connoted as "social-economic rights", has a dominantly "positive" character that arouses greater concern for questions of policy on social resource distribution, in accordance with the determination of a national scale of priorities (see Guy

Seidman and Erez Shaham, "Introduction: Medicine and the Law and What's Between Them," 6 *Law and Business* 13, at p. 27 (2007) (hereinafter: Seidman and Shaham).

Since its earliest days, the accepted view of this Court has been that the Court should be wary of intervening in the formulation of overall economic policy and in the determination of national priorities; the general rule is that the executive and the legislative branches shoulder the public and national responsibility for the State economy (see my comments in HCJ 4769/95 Menahem v. Minister of Transport [7], para. 13, and references cited there). Bearing this in mind, and in the absence of an explicit anchoring of social rights in basic legislation, the question that arises is to what extent can judicial-interpretative tools be used to construe the rights enumerated in Basic Law: Human Dignity and Liberty as including a right with a correlative duty to provide public healthcare services on a larger scale than that of the minimum requirements for decent human existence in a society (regarding this matter, cf. the majority opinion, as per President A. Barak, with which I concurred, in HCJ 366/03 Commitment to Peace and Social Justice Society v. Minister of the Interior [8], paras. 14-16 - that the constitutional right to human dignity includes the protection of the "minimum" for decent human existence, as opposed to the minority view of Justice E. Levi (*ibid*, paras 1-3), according to whom human dignity includes protection of "appropriate living conditions"; for a view in favor of a broad interpretation of the constitutional right to human dignity in the realm of welfare and social security, see e.g. Yoram Rabin, The Right to Education, at p. 370 (2002) and references cited; for other views see: Ruth Gavison, "The Relations between Civil-Political Rights in Israel and Socio-Economic Rights," Economic, Social and Cultural Rights in Israel, 25, at pp. 34-35 (eds. Yoram Rabin and Yuval Shani, 2004); Rivka Weil, "The Health of the Budget or the Health Budget – Which Takes Preference from a Constitutional Perspective?" Law and Business 6, 157, at p. 169ff (2007) (hereinafter: Weil); Yoav Dotan, "The Supreme Court as the Protector of Social Rights" Economic, Social and Cultural Rights in Israel, at p.69 (eds. Yoram Rabin and Yuval Shani)).

It will be pointed out below that recognition of a constitutional right to publicly funded health services raises the question of the degree of constitutional protection of that right. In other words, even assuming that the

right is included, be what may the scope, in the framework of the constitutional rights enumerated in Basic Law: Human Dignity and Liberty, this does not mean it is absolute; like other rights, the right to publicly funded health services must be balanced against other competing rights and interests. Accordingly, if a constitutional right to public health services is established, the question to be considered is how to interpret and apply the conditions of the reservation clause under circumstances in which it is proved that there was a substantive violation of that right, and what are the appropriate tools for giving effect to those conditions. (On the distinction between the internal scope of a constitutional right and the extent of protection accorded to it, see Aharon Barak, *Legal Interpretation*, Vol. 3, Constitutional Interpretation (1995), at p. 371ff.

11. These dilemmas are complex, and they trigger questions relating to various aspects, which I will not discuss here. I will simply mention that the right to health has indeed gained recognition in various international conventions, and it is included in the constitutions of a number of states around the world. Nevertheless, the delineation of the internal scope of the right and the extent to which it is protected remain vague, and they are characterized by a cautious approach that considers the budgetary capabilities of each state and the principle of the progressive realization of the right. For example, in 1946 the Constitution of the World Health Organization (WHO) recognized the basic right to health, but the scope of this right is defined as "the highest attainable standard of health" [emphasis added – D.B]; (see also: Eval Gross, "Health in Israel: Right or Commodity?" Economic, Social and Cultural Rights in Israel, 437, 442-443 (Yoram Rabin and Yuval Shani eds, 2004) (hereinafter: Gross). As for the Universal Declaration of Human Rights of 1948: this Convention entrenches a number of social human rights, including the right to a decent standard of living which includes aspects of the right to health and to medical treatment. At the same time, the Preamble to the Declaration states that these rights are to be realized by "progressive measures".

One of the central international documents concerning the right to health is the International Covenant on Economic, Social and Cultural Rights of 1966, which was ratified by the State of Israel in 1991. Section 12 of the Covenant states that Party States to the covenant "... recognize the right of everyone to the enjoyment of the highest *attainable* standard of physical and mental health" [emphasis not in original – D.B], and that the States must take the required steps to ensure, *inter alia*, "the creation of conditions which would assure to all medical service and medical attention in the event of sickness." Section 2 of the Covenant adds that each Party State will take steps "...to the *maximum of its available resources*, with a view to *progressively* achieving the full realization of the rights" (on other international conventions and documents on the right to health, see: Gross, at pp. 443-445). Thus we see that the international conventions that recognize the right to health and medical treatment take budgetary constraints into consideration, and are cautious in determining the scope of this right and the degree of protection it is accorded.

On the internal constitutional level, the constitutions of many states, including Canada and the U.S.A, do not confer explicit constitutional status upon the right to health. The constitutional law of these states protects only limited aspects of this right. On the other hand, s. 27 of the South African Constitution confers explicit constitutional status upon the right of access to medical treatment. However, the South African Constitution adds that the state must take reasonable legislative and other measures, within its available resources, to achieve the progressive realization of each of these rights (for text of the South African Constitution. the see http://www.info.gov.za/documents/constitution/1996/96cons2.htm#27). It should be noted that the constitutions of India and Holland expressly entrench the right to promote public health, but this right is not enforceable by the judiciary and it is only a type of fundamental principle that is intended to guide the actions of the executive and the legislative authorities (see Gross, at pp. 462-463; Guy Seidman, "Social Rights: A Comparative Perspective on India and South Africa," (347, at pp. 356, 370) (Yoram Rabin and Yuval Shani eds, 2004)).

A comparative analysis reveals that while the right to health and medical treatment is recognized on the international level and in the constitutions of several states world-wide, the scope of this right, the degree to which it is protected, and the manner of its realization vary from state to state, and are characterized by a cautious approach that is influenced, *inter alia*, by the availability of public resources and by the economic capabilities of each state

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(see Aharon Barak, "Introduction," Economic, Social and Cultural Rights in Israel, 8-9 (Yoram Rabin and Yuval Shani eds, 2004)). In general, the question of the scope of public health services is not exclusive to Israel and it characterizes, in varying degrees, to all states in the world, for no state is capable of funding unlimited health services, which are constantly becoming more sophisticated and more expensive due to medical and technological developments. The system for funding health services provided to the public also varies from state to state according to different models (private funding, public funding or a combination thereof), in accordance with the economic regime governing that particular state, its social priorities, and its budgetary capabilities (see Seidman and Shaham, at pp 40 - 42; on the system for funding health services in Canada, the U.S.A and England, see Yuval Karniel, "The Basket of Medications - Doctors, Judges and the Media," Law and Business 6 (2007), at pp. 225, 231 (hereinafter: Karniel)). Our case-law has already held that "[e]ach state has its own problems. Even if the fundamental considerations are similar, the balance between them reflects the particularity of each society and that which characterizes its legal arrangements" (per President A. Barak in HCJ 4128/02 Man, Nature and Law v. Prime Minister [2], at para. 14). Against the background of the above, it can be said, in sum, that the definition of the scope of the constitutional right to public health services, the extent of its constitutional protection, and the provision of measures for its enforcement are complex issues. As such our treatment of the right in case law requires caution and moderation.

12. The petition in HCJ *Sheiber* does not require a decision on the entire complex of questions pertaining to the constitutional status of the right to medical treatment in general, and the right to publicly funded health services in particular. This is because the petition is not concerned with the constitutionality of a Knesset statute; rather, it concerns the manner in which the competent authorities exercised their discretion in determining the contents of the health services basket. Bearing that in mind, I will confine myself to a short comment on the constitutional aspect as it relates to the circumstances of this case.

As mentioned, the petition in HCJ *Sheiber* is directed against the noninclusion of Erbitux in the publicly funded health services basket. Erbitux is an innovative medicine for the treatment of colon cancer. As will be

elucidated below, there is no consensus regarding the effectiveness of this medication in the saving or even the prolonging of life; the research data from studies of this medication are still disputed, and the medication is expensive. I therefore tend to the view that this particular medication, and other similarly experimental innovative medications, would not fall within the rubric of the *basic* health services required for minimal human existence in society. Indeed, for patients suffering from life-threatening illnesses, any medication that offers some chance to save or at least to prolong their lives, even if only for a short time, is of critical, inestimable value. At the same time, from a broad social perspective and given the limitations of the public resources, I doubt whether the demand for public funding for these innovative medications has a handle in the hard kernel of constitutional rights enumerated in the Basic Law.

Furthermore, even according to an exegetical approach that extends the constitutional scope of the right to human dignity beyond the level of the basic minimum in the area of welfare and social security, it would appear that only in extreme and exceptional circumstances would the state be constitutionally obligated to fund a specific medication, one of many in respect of which applications are submitted for public funding. In this than necessary in national context, it is noteworthy that in view of their reluctance to intervene more -economic scales of priorities, courts the world over refrain from ruling that the lack of public funding for a concrete medical treatment amounts to a violation of the patient's constitutional right. (For exceptional circumstances in which it was ruled that a violation of a constitutional right had been proved, see and compare: Minister of Health v. Treatment Action Campaign, CCT 8/02 [31]. In that case, the South African Supreme Court obligated the Government to enable the distribution of medicinal treatment designed to prevent the transmission of the AIDS from mothers to their children, under circumstances in which the medicine was provided free of charge to the Government by the manufacturer). Considering all the above, it would appear that in the petitioners' case it has not been proven that a meta-legal constitutional right has been violated, and their rights must be thus be examined in accordance with the normative-legislative framework that will be discussed below.

The legal right to public health services

13. As noted, HCJ Sheiber is not concerned with the constitutionality of Knesset legislation, and consequently I saw no need to rule on the complex of questions arising with respect to the constitutional status of the right to publicly funded medical treatment. It should however be stressed that the right to public health services exists in its own right as a *legal* right, in other words, as a right that stems from Knesset legislation as interpreted in case law and in the spirit of the obligations of the State on the internationalconventional level, with no necessary connection between the aforementioned legal right and the constitutional rights enumerated in Basic Law: Human Dignity and Liberty (cf. the right to education: HCJ 2599/00 Yated Association of Children with Down Syndrome v. Ministry of Education [9], para. 6, per Justice D. Dorner and references there; HCJ 7351/03 Rishon Le-Zion Municipal Parents Committee v. Minister of Education, Culture and Sport para. 4 of my judgment). The question therefore arises as to the [10]. substance and scope of the *legal* right to public health services in Israel, and whether this right been unlawfully violated in the circumstances of the petitioners' case.

14. The scope of the State's responsibility to ensure the access to and provision and funding of health services in Israel is set forth in our legal system in various pieces of legislation. S. 3(a) of the Patient's Rights Law, 5756-1996 (hereinafter: "Patient's Rights Law"), entitled "The Right to Medical Treatment" prescribes as follows:

 (a) Every person in need of medical care is entitled to receive it in accordance with all laws and regulations and the conditions and arrangements obtaining at any given time in the Israeli health care system.

S. 3(a) of the Patient's Rights Law explicitly provides that the scope of the right to medical treatment in Israel derives, *inter alia*, from the statutory provisions applying to the matter. It should be mentioned that s. 5 of the Patient's Rights Law, entitled "Proper Medical Care" supplements the provision of s. 3(a) in providing that: "A patient shall be entitled to proper medical care, having regard both to its professionalism and quality, and to the personal relations incorporated in it." S. 3(b) of the Patient's Rights Law

(b) In a medical emergency, a person is entitled to receive unconditional urgent medical treatment.

It should be stated immediately that the petitioners avoided basing their claims before us on the provisions of s. 3(b) of the Patient's Rights Law. Indeed, it would appear, *prima facie*, that under its current categorization, Erbitux "could not qualify as urgent medical treatment for a medical emergency under the provisions of s. 3(b); it is a relatively new medication, intended to prolong life under circumstances of grave protracted illness; the research data regarding its categorization is disputed, and it is not included in the basket (see the ruling of the South African Constitutional Court, whereby the right to "emergency medical treatment" under s. 27(3) of the Constitution does not apply to dialysis treatment given for the sake of prolonging life in a chronic medical condition of a protracted illness: *Soobramoney v. Minister of Health* [32]). It should be mentioned that in the circumstances of the case before us, similar reasons underlie the non-application of the provisions of the Do Not Stand on Your Neighbor's Blood Law, 5758-1998 [Israeli Good Samaritan Law- *trans*], which the petitioners cited in their pleadings.

15. Another major piece of legislation with ramifications for the substance and the scope of the *legal* right to public health services is the National Health Insurance Law. Prior to the enactment of this Law, health insurance in Israel was voluntary. There was no legal obligation to take out medical insurance, and a person not insured as a member of one of the Sick Funds was obligated to pay for all medical treatment that he received (on this matter see CA 5557/95 Sahar Insurance Company Ltd v. Alharar [11], para. 12 per (former title) Justice Theodor Or). The National Health Insurance Law was designed to change this situation. The purpose of the Law was to create a compulsory health insurance system in order to guarantee health services for the entire Israeli population, while defining the funding sources of the public health system and their allocation. The National Health Insurance Law was based on recognition of the state's responsibility for funding public health services for the general benefit, to be provided to the public by way of the Sick Funds, deriving from the state's commitment to "principles of justice, equality and mutual assistance" as stated in s. 1 of the Law.

The substance and the scope of the legal right to public health services are laid down in s. 3 of the National Health Insurance Law, entitled "The Right to Medical Services", which provides as follows:

- 3. (a) Every resident is entitled to health services under this law, unless he is entitled to them by virtue of another law.
  - •••

(b) The State is responsible for the funding of the health services basket from the sources enumerated in section 13.

(c) The Sick Fund is responsible to any person registered with it for all of the health services to which he is entitled under this law.

(d) The health services included in the health basket shall be provided in Israel, according to medical discretion, of a reasonable quality, within a reasonable period of time, and within a reasonable distance from the insuree's residence, *all within the framework of the funding sources available to the Sick Funds under section 13.* 

(e) Health services will be provided while preserving human dignity, protection of privacy and preserving medical confidentiality [emphasis not in original – D.B.]

From the provisions of s. 3 and the other provisions of the National Health Insurance Law, it emerges that a special relationship between the insured parties, the Sick Funds, and the State is established in that Law. The Law obligates the insured parties – consisting of all residents of the State – to pay insurance premiums at a progressive rate calculated in accordance with the insured party's level of income, as specified in s. 14 of the Law. This gives expression to the principle of mutual responsibility, the aspiration being for each insured party to pay according to his ability and receive according to his needs, out of consideration for the weaker members of society (see: *Report of the National Committee of Inquiry for Examining the Operation and Effectiveness of the Israeli Health System*, vol. 1, 81 - 82 (1990) (hereinafter: Netanyahu Report); Carmel Shalev, *Health, Law and Human Rights* (2003), 202 (hereinafter: Shalev); on the principle of detaching the receipt of medical treatment from the ability to pay for it, and the gradual erosion of this

principle over the years due to amendments introduced into the National Health Insurance Law, see Gross, at p. 471 ff).

Under the provisions of the National Health Insurance Law, the Sick Funds are responsible for providing all their registered insured members with all of the health services under the Law, apart from a limited number of health services, the provision of which is the responsibility of the Ministry of Health (see s. 3(c) as cited above, and s. 69 of the Law). The health services that insured members are entitled to receive directly from the Sick Funds are mainly those health services included in the "health services basket" as defined in s. 7 of the Law. It should be noted that prior to the enactment of the National Health Insurance Law, there was no uniform basket of services, and each Sick Fund exercised independent discretion in its determination of the healthcare services to be provided to its members, regarding both the composition and the scope of services. The National Health Insurance Law changed this situation by fixing a single basket that was binding upon all of the Sick Funds.

Whereas the Sick Funds are responsible for the provision of the services included in the public health services basket, the State is responsible for funding the basket. The National Health Insurance Law contains specific provisions relating to the calculation of the cost of the basket, and to the sources from which it is funded. Section 9(a) of the Law fixes the "basic cost" of the basket; this is updated annually in accordance with an automatictechnical formula that is based on the rate of increase of the health cost index as specified in the Fifth Schedule of the Law. Once the cost of the basket for a particular budgetary year is set, the State is responsible for funding the basket by means of the funding sources listed in s. 13 of the law. Section 13 contains a list of sources for funding the healthcare services provided under the Law, including health insurance dues paid by insured members, sums of money collected by the National Insurance Institute, certain sums from the budget of the Ministry of Health, and others. The funding sources for the basket include "additional sums from the state budget as determined annually in the Budget Law, and which supplement the funding of the cost of the basket borne by the Sick Funds ...". Thus, the annual Budget Law serves as a central funding source that supplements the other statutory funding sources of the health services basket.

It should be mentioned as an aside that over the years, there has been extensive criticism of the statutory mechanism for adjusting the cost of the basket. The main objection in this context is that the health cost index is inadequate for the purpose of adjusting the funding of the health services basket to the real increase in the cost of the basket which stems, inter alia, from the growth in the national population, the increase in the average age of the Israeli population, and the constant technological progress in the field of medicine (see Shalev, at pp 229 - 232, 269-270; Gross, p. 495 ff; Daphne Barak-Erez, "The Israeli Welfare State - Between Legislation and Bureaucracy," 9 Labor, Society and Law 175, at p. 181 (2002); see also HCJ 2344/98 Macabb Health Services v. Minister of Finance [12], per (former title) Justice M. Cheshin)). Over the years, the Finance Ministry rejected recommendations for the establishment of a substantive mechanism to supplement the technical mechanism currently fixed by the Law on grounds of budgetary constraints. A number of petitions contesting this conduct were submitted to this Court, but ultimately this Court refrained from intervening in the aforementioned policy of the Finance Ministry, for the reasons outlined in the decisions (see HCJ 9163/01 General Health Services v. Minister of Finance [13], per (former title) Justice M. Cheshin; see also Macabbi Health Services v. Minister of Finance [12]). Various draft laws for establishing a substantive mechanism for adjusting the real cost of the health services basket did not evolve into legislation. This being the situation, the Government retains broad discretion in determining the amount of the annual supplement to the cost of the basket, above and beyond the supplement mandated by the health cost index.

16. The entire body of arrangements prescribed by the Patient's Rights Law and the National Health Insurance Law leads to two main conclusions regarding the substance and the scope of the legal right to public health services in Israel. *First*, given that the purpose of the National Health Insurance Law is to grant rights to all residents of Israel by way of a national health insurance, as opposed to private risk insurance; and given that the public health services basket are subject to the funding sources listed in s. 13 of the Law, among them the Annual Budget Law - it is clear that the health services, at the optimal scope and level as

may be required by an individual. This point was made by (former title) Justice T. Or, writing as follows:

"...As we saw, the Health Law establishes a basket of services. It does not purport to provide all of the medical services that are or may be required by those insured by the Sick Funds...the existence of a health system is dependent upon its financial balance, and the existing financial sources do not guarantee the provision of all the possible medical services...

It thus emerges that the provision of medical services by the Sick Funds cannot always provide all of the medical services required by a sick or injured person who is insured by the Fund'(CA 5557/95 *Sahar* [11], para. 19).

Secondly, the purpose of the National Health Insurance Law and the body of arrangements it prescribes, and s. 5 of the Patient's Rights Law which determines the right to 'proper medical service' - necessitate the conclusion that at this point in time, our legal system recognizes a legal right to public health services that extends beyond the minimum core of basic health services required for decent life in a society. Naturally, it is difficult, perhaps even impossible, to define precisely the scope of this legal right. Nevertheless, we can speak of a right with a core and an outer casing. The core of the legal right to public health services includes all the public health services that the state is obligated to fund. Section 7(a) of the National Health Insurance Law classifies these as the "basket of basic services" provided by the General Histadrut Sick Fund prior to 1.1.94 (just before the Law came into force); with the addition of the automatic technical adjustment in accordance with the health cost index as specified in s.9(b) of the Law (hereinafter: the basic basket). The public funding of this basic basket constitutes a defined statutory obligation in terms of its scope and quantity, and indisputably, the state is powerless to shake off this obligation by claiming that there is no budgetary coverage for its liability (see and compare: HCJ 1554/95 Supporters of Gilat Amuta v. Minister of Education, Culture and Sport [14], per (former title) Justice T. Or, at para 21; HCJ 2344/98 Macabb Health Services v. Minister of Finance [12]; HCJ 2725/92 Macabbi Health Services v. Minister of Finance [15], per Justice S. Joubran, at para. 47).

Within the outer casing of the basic right to public healthcare services are all other health services that are not included in the framework of this basic basket. Pursuant to the provisions of the National Health Insurance Law, the right to extend the health services basket beyond the basic basket is a right of the type that (former title) Justice Cheshin dubbed "budget-dependent rights" (Macabbi Health Services v. Minister of Finance [15], paras. 35-40). By their very nature and essence, these rights are a function of the policy that has its source in the Annual Budget Law. Indeed, as explained above, s. 13 of the National Health Insurance Law states that the Annual Budget Law shall serve as a funding source that supplements the other sources of funding of the health services basket. This means that the Budget Law determines the additional funding for the addition of new technologies and medications to the health services basket, such that "without a budget there is no right" to the expansion of the basket (see and compare: Macabbi Health Services v. Minister of Finance [15], at p. 39). This arrangement may indeed be consistent with the conception endorsed by international conventions and in the legal systems of other states, whereby the scope and extent of realization of the right to health and medical treatment is subject to the economic capability of the state and the resources at its disposal (see para. 11 ibid).

17. Under the current legal position, the scope of the legal right to public health services beyond the basic basket derives from the Annual Budget Law. At the same time, I should mention that the budgetary limitation is not a permanently unsurpassable ceiling. The International Covenant on Economic, Social and Cultural Rights, which, as noted, was ratified by Israel in 1991, determined that the State Parties must take steps for the progressive realization of the right to health recognized in s.12 of the Covenant. The meaning of the obligation of progressive realization was discussed in General Comment 14 of the U.N. Committee on Economic, Social and Cultural Rights - which is the authorized interpretation of s.12 of the Covenant. General Comment 14 provides inter alia that in circumstances in which retrogressive measures are taken that impede the progress already achieved in relation to the right to health, the State party has the burden of proving that the measures are necessary in view of the State party's maximum available resources (see para. 32 of General Comment 14 ibid). This, then, is the position on the level of the conception of the international undertakings. In the spirit of these principles

the question that is likely to arise in our legal system is whether a serious reduction in the funding of the health services basket - including by way of significant cumulative erosion of the funding of the basket in the absence of a substantive mechanism for a real adjustment of its cost - transfers the burden to the State to show that this reduction is indeed justified and dictated by reality. The question is one of interpretation: the legal right to the expansion of the health services basket is indeed budget-dependent in accordance with the provisions of the National Health Insurance Law, but the question is whether it is appropriate to interpret its scope taking into consideration the principle of progressive realization, and in the spirit of Israel's undertakings on the international level? This question is not currently under discussion and I prefer to leave it as pending.

18. In the circumstances of this case, does the non-inclusion of Erbitux in the Health services basket unlawfully violate the petitioners' *legal* right to receive publicly funded health services? There is no dispute that Erbitux was not included in the basic basket as defined in s. 7 of the Law (see para. 16 *supra*). Therefore, the demand for public funding for Erbitux is "budget-dependent". In this context it should be stressed that the petitioners in HCJ *Sheiber* refrained from challenging the budgetary framework allocated by the Government for the expansion of the health services basket, and rightly so under the circumstances. In both his oral and written pleadings, counsel for the petitioners stressed that the petition is not aimed at increasing the budget earmarked for the health services basket; it is directed primarily against the authority of the Committee and the manner in which it exercised its discretion in determining the contents of the health services basket in the framework of the existing budget.

I will state right away that we have examined the petitioners' arguments against the Committee's authority and its mode of operation, and our conclusion is that there are no legal grounds for our intervention on that count; nor has it been proven, in the circumstances of the case, that the petitioners' legal right to receive public healthcare services was unlawfully violated. In order to elucidate our reasons for this conclusion, we will first consider the manner of determining the composition of the health services basket, the nature of the Committee and its subordination to the rules of public law. We will then proceed to discuss the petitioners' arguments against the authority of

the aforementioned Committee and the manner in which it exercised its discretion.

#### Determining the composition of the health services basket

19. As mentioned, s.7 of the National Health Insurance Law defines the initial contents of the health services basket (the basic basket), in a manner that reflects the framework of health services that were provided by the General Histadrut immediately prior to the date on which the Law came into force. Naturally, in view of the rapid developments in the world of science, and taking into consideration the accelerated development of new medical technologies in the face of the steadily increasing needs of the Israeli population, it frequently becomes necessary to examine the possibility of adding new medications and technologies to the health services basket. In this context, s. 8(e) of the National Health Insurance Law prohibits the addition of medications and technologies to the health services basket in the absence of a suitable funding source to cover the additional cost involved (on the questions of interpretation raised by this section, see HCJ 1829/02 General Health Services v. Minister of Health [16], per Justice E. Grunis, para. 5). Section 8(b)(1) of the National Health Insurance Law further provides that any addition of new medications and technologies to the health services basket involving additional costs must be by virtue of a decision of the Health Minister, with the agreement of the Minister of Finance and the approval of the Government.

20. When there has been a decision to allocate a budgetary supplement to fund an expansion of the health services basket, how is it decided which new medications and technologies to include in the framework of the basket? As transpires from the State's response, the adoption of decisions on this matter is subject to a complex process comprising several stages:

Each year the Ministry of Health sends out a "public appeal" for the submission of requests to include new medications and technologies in the Health services basket. The requests are submitted by a variety of bodies – professional, public, commercial and private. After collecting the requests, the process of gathering data and professional evaluation begins. This process is conducted by the Technologies and Infrastructure Administration in the Ministry of Health, with the assistance of additional professional bodies both inside and outside the Ministry of Health. Upon completion of this process,

and after the formulation of the recommendation of the professional bodies in the Ministry of Health, the professional background material is transferred to the Committee.

This Committee conducts its deliberations regarding the requests submitted to it, taking into account all the professional material made available to it. From the State's response, it emerges that at the initial stages of the Committee's deliberations, each medication is evaluated and graded numerically in order to serve as an auxiliary tool for the basic classification of the various technologies. At the advanced and final stages of the deliberations, the Committee prioritizes the various technologies and recommends the adoption of a final scale of priorities among the technologies, taking into account the given budgetary framework.

The Committee's recommendations regarding the ranking of new medications and technologies are presented to the plenum of the Health Council, which is authorized under the Law to advise the Minister of Health on changes in the basket. Following all these stages, and in the event that the recommendations are accepted by the Minister of Health, they require the consent of the Minister of Finance and confirmation of the Government, pursuant to s. 8(b)(1) of the Law, for the purpose of confirming the funding sources for the expansion of the basket. At the end of the process the recommendations are anchored in an Order issued by the Minister of Health.

The Committee thus plays a central role in ranking the new medical technologies, and its recommendations affect the contents of the basket in the event of a budgetary decision being adopted for its expansion. We will now focus our attention on this Committee.

### The nature of the committee and its subordination to the rules of public law

21. The Committee is appointed by virtue of an administrative decision of the Minister of Health, and it operates on behalf of the Health Council, which is authorized to advise the Minister on matters pertaining to "changes in the health services basket, taking into account, *inter alia*, new technologies and their costs (s. 52(1)(b) of the National Health Insurance Law). The authority to appoint the Committee is found in s. 48(f) of the National Health Insurance Law, which provides that the Health Council, headed by the Minister of Health, is authorized to appoint committees from amongst its members, and to have recourse to experts who are not members. The appointment of the

Committee might also be anchored in the general ancillary competence of the Minister of Health to voluntarily consult with others in the exercise of his authority, and to establish suitable bodies for the purpose of such consultation (see s. 17(b) of the Interpretation Law, 5741-1981; and see Itzhak Zamir, *Administrative Authority*, vol.1, at pp. 190-191, 246-247 (1996) (hereinafter: Zamir)).

The Committee's role, therefore, is to advise the relevant bodies on the prioritization of new medical technologies for the purpose of expanding the health services basket. Work of this kind undoubtedly requires expertise, experience and broad understanding in order to strike the appropriate balance between all of the relevant considerations, which are multi-disciplinary and complex, as will be specified below. With this in mind, the Minister of Health, in conjunction with the Minister of Finance, decided to include experts from different fields on the Committee: representatives of the doctors, representatives of the Sick Funds, economists, and public representatives. This composition of the Committee was designed to assist it in evaluating new medical technologies and accepting recommendations from a broad social perspective, taking into consideration the professional-medical aspects and the various public considerations involved in the addition of new medications and technologies to the medical services basket, all within the framework of the resources allocated by the Government to the health services basket for the relevant budgetary year.

22. It should be stressed that although the Committee is not a statutory body, and although it includes public representatives who are not personally subordinate to the appointing minister, the Committee is part of the public administration and its actions are governed by the rules of public administration (on the proposal to refer to bodies of this kind as "satellite bodies", see Zamir, at p. 413, 421). It should be mentioned that State counsel did not dispute this, and in their summations they assumed that the Committee was indeed bound by the rules of Administrative law.

In view of the above, it is agreed that the Committee is obliged to act reasonably and fairly, basing itself on relevant considerations and the principle of equality, and conducting correct administrative proceedings in the spirit of the principles laid down in the National Health Insurance Law. Furthermore, in view of the Committee's unique composition, its professionalism and its

expertise regarding the sensitive and complex questions which it considers, it is given relatively broad leeway in the exercise of its discretion. As a rule, this Court will not substitute itself for the Committee, and will not rush to intervene in the Committee's exercise of its discretion, as long as the latter's recommendations were the product of a correct process and as long as it did not deviate substantively from the framework of relevant considerations that it ought to have considered, or from an appropriate balance of these considerations within the parameters of reasonableness (cf: HCJ 7365/95 *Bolous Brothers- Marble and Granite Production Ltd v. Investments Centre* [17], *per* Justice I. Zamir, para. 4).

23. In concluding this part of the hearing, I will say that from the outset, there was no obligation to anchor the actual establishment and operation of the Committee in legislation, in that it is a body established for advisory purposes, as explained above. Over time however, the Committee has become a factor that wields major influence on the updating of the contents of the health services basket, inter alia in view of the general tendency of the Minister of Health to endorse the Committee's recommendations on prioritizing the various medical technologies. Considering the Committee's influence and the complexity of its work due to the gravity of the matters with which it deals, and in view of the pressures applied by various interested parties, this would seem to be an appropriate time to consider anchoring its activities in an appropriate statutory framework that would determine the manner of the Committee's appointment, its composition, its powers and its work procedures. Such anchorage is likely to assist in the regulation of the Committee's activities, considering the particular sensitivity of the difficult and important issues with which it deals (see and compare: Guy I. Seidman, "Regulating Life and Death: The Case of Israel's 'Health Basket' Committee", 23 J. Contemp. Health L. & Pol'y 9, 30 (2006); Karniel, at pp. 234-235; regarding other advisory bodies established by force of an administrative decision and subsequently anchored in appropriate legislation, see: Zamir, at pp. 415-416). Those responsible for these matters would therefore do well to consider appropriate statutory regulation of the Committee and its activities.

Discussion of the petitioners' arguments against the manner in which the Committee exercises its discretion

24. The petitioners in HCJ Sheiber raised several major arguments against the manner in which the Committee exercises its discretion in general, and against its recommendation not to give Erbitux a high ranking on the scale of priorities in particular. First, they argued that the Committee overrated the budgetary consideration and that its recommendations, which translated into a relatively low ranking for life-saving or life-prolonging medications, were made unlawfully, due to the failure to ascribe the requisite importance to the value of saving human life. Secondly, the petitioners challenged the criteria that guided the Committee in its prioritization of the new medical technologies. The main argument in this context was that in the framework of the budget allocated for funding the basket, the funding should be based on an equal rate for all life-saving or life-prolonging medications, without preferring one medication over others and without attaching weight to the chances of recuperation offered by the different medications. Thirdly, it was argued that the exclusion of Erbitux from the health services basket amounted to unlawful discrimination because it discriminated against the petitioners vis-à-vis other patients whose essential medications were included in the basket.

25. Having heard the parties and having examined the material in the file, our conclusion is that the petitioners' arguments should be rejected. I will preface the discussion by clarifying that under settled case law, and as part of its obligation towards the public, a public authority is permitted, and even obliged, to consider budgetary constraints in exercising its discretion. This is especially the case when the law empowers the authority to determine alone, at its own discretion, the precise scope and limits of the entitlement to a public service, in a manner that requires fixing a scale of priorities in accordance with limited public resources. As stated by Justice S. Netanyahu:

'No society has unlimited resources. No statutory authority operating in a society is permitted and able to ignore budgetary constraints and to provide services without any kind of accounting, no matter how important and urgent they may be ...

Every authority is faced with the need to strike a proper balance between the scope, the manner and the degree to which it discharges its functions-obligations under the law on the one hand, and its obligation to maintain its budgetary framework on the other. It can never fully discharge all of these and fulfill all its

functions optimally without taking budgetary restraints into account. It must establish its own scale of preferences and priorities, and guiding rules and criteria for their implementation; these must meet the test of reasonability, and be exercised on the basis of equality' (HCJ 3472/92 *Brand v. Minister of Communications* [18], para. 4; see also HCJ 3627/92 *Israel Fruit Growers Organization Ltd. v. Government of Israel* [19], per Justice E. Mazza, para. 5).

As clarified above, the National Health Insurance Law expressly prohibits the addition of services to the health services basket in the absence of a suitable source of funding. Consequently, the budgetary consideration is a legitimate and relevant one, which the Committee is entitled to consider in its prioritization of the new medical technologies. Our case law has already held that "[o]ne cannot ignore the fact that even in a matter as sensitive as health, budgetary factors must be considered," (*per* Justice A. Grunis in HCJ 2453/06 *Israeli Medical Association v. Attorney General* [20], para.3; see also Justice M. Naor in HCJ 4004/07 *Turonshwili v. Ministry of Health* [21], para. 6). This in no way implies contempt for the sanctity of human life; rather, it constitutes recognition of the inherent constraints of a reality in which budgetary resources are limited and must be divided amongst all of the national and social needs that make prioritization necessary.

26. Further to the above, it should be noted that the National Health Insurance Law is silent on the method of prioritizing the various medical technologies for purposes of expanding the basket. Nevertheless, it is settled case law that the public body's authority to allocate limited resources may also entail the authority to determine the method of allocation and the scale of priorities (see HCJ 4613/03 *Shaham v. Ministry of Health* [23], *per* Justice E. Levy, para. 7).

The Committee's job of advising the Ministry of Health and the Health Committee on the prioritization of the various medical technologies is undoubtedly an exceedingly difficult, complex and sensitive task (on the dilemmas involved, see: Netanyahu Report, at p. 100). The State attached a document to its written pleadings in which it laid out the criteria set by the Committee for ranking the various technologies and medications it considered. These criteria include the following considerations: the effectiveness of the

technology in treating the disease; the ability of the technology to prevent the disease; the ability of the technology to save life or prevent death; the prolonging of life and the anticipated quality of life; the existence of an alternative treatment and examination of the effectiveness of that alternative; experience in or outside Israel in the use of the technology; economic cost on the individual and national levels; the number of patients who stand to benefit from the medication; the anticipated benefit of including the technology in the basket in the short and long terms, and others.

These are general criteria, and they were not ranked by the Committee in order of importance or weight. The State's position on the matter was that since the subject is a particularly complex one, the perspective must be broad and comprehensive and it is not possible to adopt rigid and unequivocal rules that would lead to the creation of a type of mechanical formula for resolving the public, economic, value-based and ethical dilemmas involved in determining the scale of priorities. In this context, the State emphasized that the consideration of saving or prolonging life was accorded great weight by the Committee when ranking the medical technologies under discussion. Nevertheless, like the other above-mentioned criteria, the consideration of saving or prolonging life is neither exclusive nor determinant, due to the need to consider all the other relevant considerations such as the number of people requiring the medication, alternative treatments and their effectiveness, the patient's quality of life, the overall cost in relation to other medications and others. In this context, the State added that the medications basket is not meant to include only medications that are designed to cure existing illness: it also includes a variety of other medications, such as medications with long term preventative qualities, medications that prevent complications and aggravation of existing illnesses, and medications that very significantly affect the quality of life, such as the prevention of serious disabilities and suffering.

27. After considering the matter, we have concluded that the criteria presented could not be faulted in any way that might create grounds for our intervention. In view of the complexity of the questions confronting the Committee and the fact that they involve a variety of aspects – legal, ethical, philosophical, moral, economic and others – it cannot be said that the criteria that served the Committee were irrelevant or unreasonable to a degree that necessitates the intervention of this Court. For example, it cannot be said that

the consideration of the effectiveness of the medication and its contribution to the patient's chances of recovery is an illegitimate one, as argued by the petitioners. In circumstances in which there is a limited budget, and the countless needs must be prioritized, the effectiveness of the medication is a legitimate factor which can and should be considered. As for the criterion of the economic cost of the medications - as mentioned, the Committee is entitled to consider the budgetary aspect, and this has ramifications for the prioritization of the different medications. Accordingly, the cost of the medications constitutes a relevant factor which the Committee is permitted to take into consideration.

We would add that in view of the complexity of the relevant considerations, and considering the need for a broad value-based, public perspective in order to find the golden path between the various needs, we felt that the fact that the Committee refrained from a rigid ranking of the criteria it invoked in order of their importance could similarly not be faulted so as to necessitate our intervention. It should be recalled that the Committee's discretion is not based on minimum-achievement tests, the satisfaction of which creates an entitlement to public funding, but rather on complex and sometimes conflicting criteria by means of which the Committee is supposed to recommend which medications are to be included in the Basket and which rank lower on the scale of priorities. In view of the Committee's unique composition, its expertise and its professionalism, it would appear that we cannot dismiss the State's position whereby the Committee should be granted wide discretion that will allow it to assess the weight of the relevant considerations in their entirety from a broad and comprehensive perspective. Nevertheless, further to our recommendation in para. 23 above regarding the regulation of the activities of the Committee by way of an appropriate statutory source, it seems that suitable statutory anchorage of the criteria that should guide the Committee ought to be considered. In that framework, the question of whether it is possible and desirable to determine a hierarchy of the various criteria in order to guide the Committee in the exercise of its discretion should be considered as well.

28. As mentioned, the petitioner proposed adopting a different method of prioritization from the one currently used; this new method would grant equal funding to all life-saving or life-prolonging medications. The petitioners

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proposed that a certain percentage of the cost of all the medications be funded, without preferring any particular medication over another and without deviating from the existing budgetary framework.

Regarding this proposal, we will comment that no data relating to the feasibility of its implementation from a budgetary perspective has been presented to us. However, even if we assume, for argument's sake, that the petitioners' proposal for equal allocation to all the medications is a viable one and as stated, no data was provided on this point - it is clear that this proposal too has its disadvantages and difficulties (for example, medications which are currently fully funded would, according to the petitioners' proposal, be only partially funded, thereby increasing the degree of self-participation in relation thereto). Furthermore, there is substance to the State's claim that the petitioners' proposal is incompatible with government policy whereby priority should be given to certain medications, inter alia, in accordance with their quality and effectiveness. Prima facie, the petitioners' petition is similarly at odds with the basic conception underlying the National Health Insurance Law, i.e. that the medications basket should provide a solution not only for lifesaving or life-prolonging medications but also for a broader range of medical technologies required for the health of the population. At all events, the question of how a scale of priorities should be determined in the allocation of public resources in the area of health services is controversial, admitting a variety of views. It is not up to us to recommend the adoption of one system of prioritization over another, as long as the current criteria comply with the provisions of the National Health Insurance Law, and are based on relevant and reasonable considerations, and as long as it has not been proved that the criteria substantively upset the proper balance between the relevant considerations, or that Committee substantively and clearly deviated from the bounds of reasonability.

29. As for the decision adopted in the particular case of the Erbitux medication, forming the subject of HCJ *Sheiber*, it emerges from the State's response that this medication was registered in Israel's Drugs Registry on 10 May 2005. Before that, Erbitux was marketed to metastatic colon cancer patients according to individual permits for use of the medication by virtue of s.47A(c) of the Pharmacists Ordinance (New Version) 5741-1981. The State claims that the scientific evidence relating to this medication is relatively

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President D. Beinisch

preliminary, and it is not yet known whether the medication relieves the symptoms of patients of metastatic colon cancer or prolongs their lives. This is reflected in the protocol of the meeting of the Committee from 1 January 2004, which states the following regarding Erbitux:

'The preparation is intended for the treatment of a small group of metastatic colon cancer patients. This is a new medication that was registered in the course of 2004 in the U.S.A and in other Western states.

The existing scientific evidence regarding the preparation is not abundant, and it does not prove that treatment with the medication definitely prolongs life, but rather that it generates an increased incidence of response and a reduction of the tumor mass. It may be presumed that the reduction of the tumor mass would enhance the quality of the patient's life, but will not necessarily prolong their lives.

Committee members proposed reducing the ranking of the preparation from A9 to A8 due to the absence of sufficient evidence regarding the life-prolonging component. Others claimed, however, that although the existing evidence is limited in scope, and it does not provide proper information concerning the life-prolonging aspect, there is nevertheless evidence of reduced tumor mass and improved response to treatment. Moreover, material regarding the preparation is accumulating. It was therefore suggested to define it as (A9-) which means a lower level of priority for inclusion in the basket than other treatment technologies in which the life-prolonging component is clearer (these were defined as A9)' (Protocol of Committee proceedings, dated 1.12.04, appendix RS/6 of the respondents' response, 1-6, dated 20 May 2005 in HCJ *Sheiber*).

The Committee therefore decided to give the Erbitux medication a lower ranking as compared to the other technologies which had clearly been proven to be life-prolonging. The protocol indicates that the Committee considered relevant factors, which included the effectiveness of the medication in the treatment of sickness and the question of whether there was proven capacity to

prolong life. It should be stressed that the protocol subsequently states that "material regarding the preparation [Erbitux] continues to accumulate," and that if additional significant evidence were to be received regarding, *inter alia*, its degree of effectiveness, it will be passed on to the Committee, and the medication will be brought up for further discussion. It may thus be presumed that to the extent that new scientific evidence is gathered regarding the effectiveness of Erbitux, renewed consideration will be given to the ranking accorded to this medication.

Considering all the above, it cannot be said that the Committee's recommendation regarding the ranking of Erbitux is unreasonable to a degree that requires this Court's intervention. Nor can it be said that the Committee's recommendation regarding Erbitux constitutes unlawful discrimination against the petitioners vis-à-vis other patients whose required medications are included in the health services basket. Under circumstances in which the public resources are insufficient to satisfy all the needs and all the needy, resources must be allocated according to a scale of priorities, which naturally gives rise to distinctions between various individuals and various groups. These differences do not constitute unlawful discrimination, as long as they are based on relevant, reasonable considerations (see and compare: HCJ 1113/99 Adallah v. Minister for Religious Affairs [24], per Justice I. Zamir, para. 5). Any other approach would preclude any possibility of distributive decisions for purposes of allocation of public resources, even in circumstances in which the decisions were adopted on the basis of lawful considerations. In the words of Justice E. Rubinstein:

'...[P]rioritization is essential under the circumstances of the health services basket –"The couch will always be too short for stretching out, and a handful will never satiate the lion". In a world of rapidly changing medical and technological scenes, often beyond recognition, but in which the costs of the technology and medications is high, there is no escaping the need to fix scales of priorities. *It is hard to say, even in painful cases such as this, that there is discrimination due to the prioritization*' (HCJ 2974/06 *Israeli v. Committee for Expanding the Health Services Basket* [25]) [emphasis added – D.B.].

One can certainly understand the deep distress of the patients suffering from metastatic colon cancer, whose physicians have prescribed treatment with Erbitux and who cannot afford to purchase this medication. Nor can one be indifferent to the pain and cries of the sick. We are aware that unfortunately, our conclusion denies them what they seek. Nevertheless, at this point in time, and considering the existing data, we have no legal grounds for intervening in the scale of priorities that was fixed by the Committee with respect to this medication. This being the case, and in view of all the reasons discussed above, the petitioners' request to order the inclusion of the Erbitux medication in the health services basket is denied.

The petitioners' proposals for reducing the prices of medications not included in the basket

30. A significant portion of the petitioners' claims in HCJ *Sheiber* focused on proposals aimed at reducing the prices of medications *not* included in the health services basket. In this context, the petitioners applied for two remedies, in respect of which an order *nisi* was originally issued: the *first* was to order the cancellation of value added tax and other indirect taxes levied on innovative, life-saving medications that are not included in the health services basket; the *second* is to order the respondents – the Ministry of Health and/or the Sick Funds – to make centralized purchases of these medications, to help in reducing their prices for the consumers.

As for the petitioners' request to order the cancellation of value added tax and other indirect taxes levied on medications for the disease of cancer, it emerges from the State's response that the requested cancellation of V.A.T and other indirect taxes would require a legislative amendment in order to establish a statutory exemption for medications not included in the health services basket. In this context, it should be mentioned that over the past few years, a number of private members' bills have been tabled for the amendment of s. 31 of the Value Added Tax Law, 5736-1976, with the aim of establishing an exemption from V.A.T for innovative, life-saving medications not included in the basket. These proposals did not reach the legislative stage because the Finance Ministry refused to deviate from the principle of tax uniformity and to subsidize the funding of these medications other than by way of direct support for the health services basket. At all events, the question of whether to grant a statutory exemption from V.A.T. and from other indirect taxes for new

medications not included in the health services basket lies within the responsibility of the legislature and not of this Court.

31. The responses of the Sick Funds to the petitioners' request to obligate the respondents to carry out a centralized purchase of new medications such as Erbitux in order to reduce the price for the consumers, indicate that some of them take a positive view of the idea of a centralized purchase, albeit conditional upon appropriate arrangements, legislative and otherwise, being made which would enable them to make the purchase. Other Sick Funds felt that the centralized purchase of medications not included in the health services basket should be carried out by a central body unrelated to the Sick Funds. From the parties' pleadings before us, it emerges that implementing the proposal of centralized purchase of the medications would give rise to legal problems, *inter alia* from the perspective of creating a restrictive arrangement. Furthermore, the centralized purchase of medications not included in the health services basket would involve a number of implementation-related questions, the answers to which are far from simple. What is the appropriate body to deal with the centralized purchase? How would it decide which medications to include in the purchase? Where would the medications be stored, and how would they be sold to the patients in need of them, and other similar questions. At all events, it appears that the centralized purchase of new medications such as Erbitux, which are not included in the health services basket, would in certain cases contribute to the reduction of the price of these medications for patients requiring them, and thus ease their plight. Bearing this in mind, all the relevant aspects of this proposal should be examined by the Ministry of Health and the other relevant bodies, in order to consider the issue in depth.

32. Finally, it should be noted that the petitioners in HCJ *Sheiber* requested that an order be given to issue a Supervisory Order pursuant to the Services and Commodities (Supervision) Law, 5756-1996, that would establish a ceiling price for Erbitux and for other similarly innovative medications. In the course of these proceedings, it emerged that a supervisory order of this kind had already been issued, and that the order also applies to medications not listed in the Drugs Register (see Supervision Order over the Prices of Commodities and Services (Maximum Prices for Prescription Preparations), 5761-2001; see also HCJ 3997/01 *Neopharm Ltd v. Minister of* 

*Finance* [26], in which a petition against the validity of the Order was dismissed). It was in consideration of this that no order *nisi* was given in the first place regarding that particular matter. It further bears note that in their pleadings before this Court the petitioners claimed that the Sick Funds should reorganize their funds, and utilize the budgetary balance for the purchase of life-saving medications. This claim was made in rather laconic and general manner, and we therefore did not deem it necessary to discuss it.

33. I therefore propose to my colleagues to rule as follows:

(a) In view of the addition of Avastin and Taxotere under the requested classifications to the Health services basket as of 2006, the order *nisi* given in HCJ *Louzon* shall be cancelled, and the petitions in HCJ *Louzon* and HCJ *Bar-On* shall be deleted, without any order for costs.

(b) For the reasons specified above, the order *nisi* issued in HCJ *Shieber* shall be cancelled and the petition denied, without an order for costs, bearing in mind the recommendations made in para.s 23 and 27 of my comments above regarding the regulation of the Committee's activities by way of an appropriate legislative framework.

Justice A. Grunis

I agree.

# Justice M. Naor

1. I agree that the order *nisi* given in HCJ *Louzon* should be cancelled and the petitions in HCJ *Louzon* and HCJ *Bar-On* struck down, without an order for costs. I also agree to the cancellation of the order *nisi* issued in HCJ *Sheiber*, and to the denial of the petition without an order for costs.

2. As my colleague the President has shown, the task of prioritization is a difficult one, quite often requiring us to turn our backs on the gravely ill, such as in HCJ *Sheiber*. Indeed, it is hard to face a person fighting for his life and leave him empty-handed. All the same, I see no possibility of intervening in this case.

From time to time petitions are filed in this Court relating to intervention in prioritization decisions (see HCJ 2974/06 *Israeli v. Committee for Expanding Health Services Basket* [25] and HCJ 4004/07 *Turonshwili v. Ministry of Health* [21] referred to by my colleague the President). In *Israeli v. Committee for Expanding Health Services Basket* [25] I concurred with the comments of Justice E. Rubinstein, as cited by the President in her opinion:

'...[P]rioritization is essential under the circumstances of the health services basket –"The couch will always be too short for stretching out, and a handful will never satiate the lion". In a world of rapidly changing medical and technological scenes, often beyond recognition, but in which the costs of the technology and medications is high, there is no escaping the need to fix scales of priorities. It is hard to say, even in painful cases such as this, that there is discrimination due to the prioritization. Indeed, the struggle over the limited cake is the reason for petitions that are filed in this Court, parallel to parliamentary and extraparliamentary public struggles. '

I repeated these comments in Turonshwili v. Ministry of Health [21], and I believe they are equally applicable to the case before us. In my view this Court has but a narrow margin for intervention in decisions of this nature. In order to render an appropriate decision on a prioritization matter, those making the decision (or recommendation) must have a broad picture. The prioritization applies to all the medications that are candidates for inclusion in the basket, all within the budgetary framework. Naturally, a hearing before the High Court of Justice focuses on one individual (or a limited group of people), and on one medication which may have the potential to save his life. Each person is an entire world and the importance of saving human life is deeply ingrained in the values of the State of Israel as a Jewish democratic state – to stand by and not offer help is difficult. On the other hand, those charged with making the decisions (and recommendations) have a broader perspective. I am convinced that decisions regarding the basket and its composition are occasions for sleepless nights for all those who must decide or recommend. But I too, like my colleague the President, see no *legal* grounds for our intervention. While the hearing in this case focused on the individual in need of the medication, in the background are many other patients whose voices were not heard, but whose plight is dire. A decision on the matter requires extensive knowledge, the weighing up of different data and a determination of their relative weight. As such the problem is a "multiple focus problem", using a term coined by Justice I. Zamir in HCJ 7721/96 Israeli Insurance Assessors Association v. Inspector of Insurance [27] at pp. 644-645:

'The problems presented for resolution in the framework of judicial review of public administration fall into two main categories. The first category includes problems involving a confrontation between two central factors: norms, interests or methods.... Problems of this nature usually require answers which are yes or no, permitted or forbidden, either/or. As such they can be referred to as dual-focus problems, as if there were two heads to be chosen between. This kind of problem

is classically suited to judicial review... a decision in this kind of case is generally an appropriate task for the court.

The second category includes problems consisting of a significant number of factors, norms, interests and paths, each of which merits consideration in the process of reaching a solution, and each of which should receive expression in the solution given... This kind of problem is multi-focal.... A problem of this kind does not admit of an answer which is yes or no, permitted or forbidden, either/or. As such it is exceedingly difficult, perhaps even impossible, to render a decision that relies on a legal rule or a balancing formula.... This task is classically suited for an administrative authority, which has the required expertise and tools to solve the problem; it can act in a flexible manner, in consultation and coordination with the agencies involved in the matter. It is not a task that is suited for the court.

This does not mean that the court will refuse to give any attention to a multi-focus problem. It is competent to deal with these problems... but it will place restrictions on its treatment of these kinds of matters. On the one hand, it is not prepared to place itself in the position of the administrative body and to discharge the task imposed upon it.... On the other hand, in the case of an illegal omission, it is prepared to order the administrative body to exercise its authority....[S]imilarly, after the administrative body has exercised its authority it is prepared to examine the legality of its act, such as the legality of the entire plan, or a part thereof.'

President A. Barak made similar comments in HCJ 82/02 Kaplan v. State of Israel, Ministry of Finance, Customs Division [28], at pp. 908-910:

'The role of the court is to determine whether the arrangement devised by the administrative authority is legal or not. The administrative authority may devise several alternatives, all of which will be regarded as legal as long as they do not exceed the boundaries of that which is permitted in the exercise of discretion.'

(And see also CA 8797 Anderman v. Objection Committee of District Committee under the Planning and Construction Law, 5725-1965, Haifa [29] at p. 474; HCJ 10/00 Ra'anana Municipality v. Inspector of Transport, Tel-Aviv and Central Districts [30] at p. 756).

There is a large number of solutions to the complex task of putting together the basket as explained by my colleague, each of which has its casualties. There is no optimal solution, nor is there a magic formula for weighing up the conflicting interests. The decision not to include the desired medication in the basket, on the basis of the extant information relating to it, does not exceed the bounds of reasonability, and we have no grounds for interfering with it; there is therefore no choice but to deny the petition.

Petition denied as per the opinion of President D. Beinisch.

25<sup>th</sup> Tammuz 5768 28 July 2008