

Out of Compassion or Out of Rights?

A Story about an Amyotrophic Lateral Sclerosis (ALS)
Human Clinical Trial

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Received: 30 June 2020; Accepted: 4 July 2021; Published: 28 September 2021

Abstract

This article examines the intersection of compassion and rights, and how the two concepts are constituted and wielded in the context of human clinical trials. Doron, an ALS patient who was recruited to a clinical trial, believed that he had the right to post-trial treatment according to the wording of an informed consent form he signed before joining the trial. However, the biotech company sponsoring the trial instead offered him ‘compassionate use’ access, i.e., access at its discretion rather than as a legal obligation on its part. I argue that under a ‘bioeconomy of value’, the human clinical trial regime has been subordinated to two competing discourses: that of compassion and that of patients’ rights. Both are interpreted and deployed differently by the different stakeholders, namely the patient, the biotech company, and the medical establishment. I argue that the adoption, by bioeconomy actors, of a social value discourse of compassion is designed to preserve a hierarchy that deprives the patient of their power and their rights. Simultaneously, this practice highlights the power of the biotech industry as a moral partner and ‘saviour’ in its relationship with patient organisations and its role as a medical–scientific actor in the Israeli healthcare system.

Keywords

Clinical trials, Compassion, Biotechnology industry, Rights, Israel.

Introduction

Doron¹ was in his 30s when he found out that he had the disease Amyotrophic Lateral Sclerosis (ALS). Shortly after, in 2012, he was recruited to an ALS genetic clinical trial being conducted in an Israeli public hospital by a biotech start-up. The trial was defined as a '2A phase' trial, its objective being to determine the safety and tolerability of a single-treatment administration of autologous, cultured, mesenchymal bone-marrow stromal cells secreting neurotrophic factors (MSC-NTF) to patients with ALS. Being at an early stage of the disease, Doron was an ideal candidate for the trial, as defined in the strict enrolment criteria set out in the trial's protocols. Twelve ALS patient-participants, including Doron, took part in the research, during which participants' stem cells were extracted from their bone marrow and then injected back into their bodies following laboratory intervention.

The informed consent form for the clinical trial held out the possibility of post-trial access to the treatment, in line with a procedure establishing the 'sponsor's statement of commitment' (SSC). The form also set out the terms of the SSC, while the SSC procedure was described in the trial's regulatory documentation. By the end of the trial, Doron felt some improvement in his condition. Optimistic about even the slightest possibility of a cure, he was willing to continue with the treatment as he had indicated on the informed consent form. Nevertheless, both the biotech company leading the trial and the hospital where it took place reneged on what appeared to be a clear commitment on their part. Instead, they offered Doron a one-time treatment under what was termed a 'compassionate use' (CU) procedure. The CU procedure did not include any commitment regarding the duration of treatment and was not contractually binding on the company.

Doron rejected this offer of treatment on CU grounds and sought to establish his rights to further treatment according to the SSC procedure. However, he found himself struggling alone against the company and the public hospital to establish this right. He discovered that his ALS community and its support organisation were unwilling to support him in his campaign because they saw his request as potentially sabotaging the company's efforts to find a cure for ALS. When he failed to persuade the company to act differently, Doron filed a suit against it in the magistrate's court.

My analysis of Doron's story traces how two competing discourses—one of compassion, the other of patient rights—were interpreted and deployed by each of the stakeholders: the company, the patient, and others including the hospital, Israel's Ministry of Health (MoH), and the ALS community. I argue that the 'compassionate use' procedure is employed by the biotech industry as a means of

1 All names are pseudonyms.

asserting both moral and economic power over the patient and the illness community. By presenting itself as compassionate, the company in Doron's case was able to retain its power in the medical–scientific hierarchy while positioning itself as a moral actor, while at the same time successfully revoking the more binding commitment created by its SSC. My aim is not just to explore the power of the clinical trials industry in this local context; I also seek to consider the terms and regulatory mechanisms of the industry, how these define the rights and health status of clinical trial participants, and the social implications that follow on from this. I argue that the use of a social value discourse by bioeconomy actors is intended to cause a shift from the political–legal arena to the social arena, minimising patients' rights and ability to exercise their power while reinforcing the positioning of bioeconomic roles and interests as legitimate social values.

Bioeconomic regime, social value, and human right

Ethnographic studies have discussed the emergence of a political economy driven by the pharmaceutical industry and its impact on healthcare systems and life. Such research has demonstrated the key role played by the global pharmaceutical and biotech industry in the human clinical trial regime. The practices of the pharmaceutical industry have been described as the 'pharmaceuticalisation of healthcare'. This has been achieved through the successful reinforcement of global trade rules, in terms defined by the market, consequently shaping the international health agenda (van der Geest, Whyte, and Hardon 1996; Petryna, Lakoff, and Kleinman 2006; Biehl 2007; Sariola et al. 2015). Such practices have also been described as new forms of governing (Lakoff 2005; Rajan 2005; Biehl 2007; Petryna 2009; Abadie 2010; Sofaer and Strech 2011; Lock and Nguyen 2011). In this regard, Nikolas Rose (2001) argued that 'biopolitics' has become 'bioeconomics', whereby medical care and health policy are formulated in economic terms. More recently, Sunder Rajan (2017) coined the term 'Pharmocracy' as a means of capturing how the global pharmaceutical industry operates to set forms of governance as a multinational corporate hegemony.

Within the framework of a bioeconomy regime, economic practices and social values become intertwined (Fassin 2011; Cooper and Waldby 2014; Palomera and Vetta 2016; Birch 2017; Reynolds and Sariola 2018). In this context, the term 'value' holds different meanings and perspectives. It can serve as a terrain within which definitions of worth or obligation are negotiated and their boundaries set (Narotzky and Besnier 2014, s4). Thus, Rajan (2017, 16) talks of 'the regimes of value', whereby the industry operates to naturalise its hegemonies through ethical values (Rajan 2017)—albeit operating simultaneously to narrow the frameworks of ethical norms (Petryna 2007). This tension between economic value and social

value has the potential to reframe our understanding of values and the motivations that lie behind their uses.

In Israeli political life, values such as the virtues of charity and compassion have been used as a way of countering the influence of neoliberalism, part of a drive to create a social elements equilibrium that stands in opposition to the overarching orientation of the 'free market' (Filc 2010). In the case of Doron's Amyotrophic Lateral Sclerosis (ALS) clinical trial, by tracing the establishment of social values—specifically human rights and compassion—I analyse the rationales that informed the actions of the various stakeholders, pursuing the motives that shape the definitions and socio-political outcomes of the concept of the bioeconomy of value.

The term 'right' is constituted by law as a source of power through which to confront the state, requiring it to act. 'Compassion', for its part, is a central value in health policy and for medical institutions (Pedersen and Obling 2019). According to Martha Nussbaum (2003), 'compassion' incorporates notions such as pity, sympathy, empathy, and expressing awareness of the suffering of others as an ethical judgment. Others have claimed that these emotions are not inherently part of the definition of compassion (i.e., Sinclair et al. 2016). However, it is broadly agreed that compassion does include emotional responses to another's suffering (Nussbaum 2003; Gelhaus 2012; Sinclair et al. 2016). Hence, it can be said that while rights are civil obligations, compassion is driven by goodwill and generosity and thus cannot be coerced or otherwise enforced.

In the bioeconomy regime, patients are defined as neoliberal subjects, evaluated according to terms defined by the market (Fisher and Ronald 2008). As patients/clinical trial subjects constitute themselves as being subject to human rights (Biehl 2006; Wehling 2011; Rabinow 1996) and to the rights of recovery (Petryna 2013), so pharmaceutical companies present themselves as being committed to human rights and social justice. Such practices have manifested repeatedly in recent years. When AIDS activists criticised governments, the industry responded by adjusting its business model to make drugs available to impoverished populations under the guise of a 'humanitarian gesture' or the imperatives of the social market (Biehl and Petryna 2013; Lock and Nguyen 2011). Additionally, patients' organisations are often characterised as 'illness-based movements' or groups mobilised around topics such as access to medicines or shifts in scientific priorities (Rabeharisoa et al. 2014; Reynolds and Sariola 2018). In other cases, such as in India, organisations have tended to operate within the framework of 'rights-based' approaches (Sariola et al. 2018).

In the case of Israel, the discourse of the ALS organisation can broadly be described as 'illness-based'. Under this bioeconomy of value, patients' rights were not protected by the company or the courts—nor even by the illness community,

which exists ostensibly for this very purpose. On the contrary, legal rights were pushed aside, the biotech company instead presenting a commitment to social values and goodwill—which fall outside of the matrix of defined rights and responsibilities, and the enforceable obligations therein, created by the legal system. In this process, ‘value’ not only encompasses the patient’s status but also constitutes the industry’s legal and social position. The company came to be viewed as a ‘natural’ member of the public health community; but at the same time, the industry strengthened the free-market rationale underpinning its business model, and through this, the hegemony of its governance.

The human medical trial regime in Israel

Israel’s healthcare system is characterised by a comprehensive public service, albeit operating alongside an expanding private health industry. Under the country’s National Health Insurance Law (1994), healthcare services are considered the entitlement of every resident. It should also be noted that the healthcare system is technology-intensive, being economically committed to the high-tech—and specifically biotech—industries. These conditions have emerged in what is a highly medicalised and commoditised society (Filc 2005).

With respect to human clinical trials, Israel lacks primary legislation governing these practices. Instead, the field is in effect regulated by a series of guidelines and commands—including the Helsinki Declaration, the Guidelines for Medical Experimentation in Human Subjects,² and the 1980 Public Health Regulations (Clinical Trials in Human Subjects). Moreover, it is the role of the medical human trials regime itself—through its own institutional review boards (IRBs), which operate as a self-regulating structure at the core of the regime—to ensure that its trials comply with these guidelines and commands, as well as with current international ICH-GCP regulations.³ By contrast, the government’s commitment to patients’ rights and ethical medical practice is underscored by primary legislation under its Israel’s Patient’s Rights Law (1996), which sets out the procedure for establishing informed consent in medical trials.

‘Sponsor’s statement of commitment’ versus ‘compassionate use’

In addition to informed consent, there are two further components in the Israeli regulation regime that concern patients’ rights, both of which are governed by secondary legislation. The first, the ‘sponsor’s statement of commitment’ (SSC), is an aspect of the regulation of clinical trials, is part of the Israeli Ministry of Health

2 Israeli regulations include the following: Public Health Regulations (Human Medical Experimentation) 1980; Patient’s Rights Law, 1996; Guidelines for Medical Experimentation in Human Subjects, 1999 (last updated: 2020); Prohibition of Genetic Intervention Law, 1999; Genetic Information Law, 1999.

3 International Conference on Harmonisation (ICH) of Technical Requirements, Guideline for Good Clinical Practice, E6 (R1) 1996.

(MoH) Directives of 1998,⁴ and forms part of the informed consent form. According to the relevant orders, the sponsor of a clinical trial is contractually obliged to provide the trial product (drug or device) to the patient-participant, free of charge, for a period of up to three years after the end of the clinical trial period or until it is added to the national ‘health basket’ of government-subsidised treatments and services. The conditions of this contract are as follows: the efficacy of the treatment in question for the patient-participant has been demonstrated; the product cannot be obtained from the MoH or the National Insurance Institute; and a recommendation from the researcher leading the clinical trial and the approval of the host hospital’s IRB have been secured.

The second component is the ‘compassionate use’ (CU) procedure.⁵ CU regulations are initiated when the medical treatment has not been registered in any form by health authorities; in cases when the patient suffers from a life-threatening disease; or when there is no suitable therapeutic alternative and the treatment cannot be generalised as part of a clinical trial. There is no legal obligation for pharmaceutical companies to make a treatment available for compassionate use.

Both procedures, the CU and the SSC, can be construed as social benefits relating to bioscience. The application of either must be approved by the relevant medical institution and the MoH, and in both cases the treatments must be provided free of charge. Each procedure, however, is underpinned by a different rationale. The SSC ensures that clinical trial participants are able to avail themselves of the benefit of experimental treatments or medicines after the end of the clinical trial. This right is not only anchored in clinical trial regulations but is also enforceable as a contractual agreement. CUs, on the other hand, are not a part of the conditions attached to participation in a clinical trial; even though they do involve financial considerations, they are not binding on either side and can only be effected through the goodwill of the company leading the trial.

Post-trial access (PTA) to a trial drug poses important ethical questions. Should participants in a clinical trial have PTA to the trial drug if information regarding side-effects is incomplete? Does this requirement help avoid—or perhaps increase the likelihood of—exploitation in cases where there is no access to appropriate healthcare (i.e., Sofaer and Strech 2011; Peterson et al. 2015)? In Israel, the rationale behind the SSC component is to guarantee the potential long-term benefits to the patient at the end of the clinical trial period. Note that while the US’s ‘Right to Try’ law makes medications available without requiring participation in the relevant clinical trial (Jacob 2015), in Israel the SSC is offered only to trial

4 Circular 98/15, ‘Contracts with Commercial Organizations for Conducting Clinical Trials in Government Hospitals.’ 1998, 2006.

5 Circular 30/06, ‘Guidelines and References to Conditions for the Director’s Agreement for Compassionate Use and Urgent Use with a Medical Product According to Regulation 29 of the Pharmaceutical Regulations, 1986’, 2006.

participants. In order to avoid the exploitation or solicitation of such participants, the SSC requires approval at both institutional and ministerial levels, at both the approval stage for conducting the experiment and then again at the SSC procedure approval stage.

Methods

The current article presents some of the findings of my research into human clinical trials in Israel. It is based on fieldwork conducted between 2013 and 2017, which included a full year of observations at two institutional review boards (IRBs) in hospitals and semi-structured interviews with 62 key players in the field of human clinical trials. My research explores the relationship between medical science, society, and the state in the Israeli context, and identifies the intersections between the industry and the medical centres.

This article focuses on Doron's case. Here, I draw mainly on three different types of data: first, semi-structured interviews with Doron and his wife Merav, physicians, and the hospital's IRB members, which included CRA (Contract Research associates) workers, policymakers, and lawyers; second, observations of legal consultations and court proceedings; and third, analyses of the National Bioethics Committee protocols, clinical trial protocols and policy documents, newsletters, and relevant social media over the five-year period between 2013 to 2018.

It should be noted that right from the beginning of my study of the Amyotrophic Lateral Sclerosis (ALS) clinical trial affair, I encountered significant difficulties recruiting additional interviewees from the trial's participants. It transpired that they were wary of public exposure, and so out of respect and acknowledgement of their difficult position I decided not to try to persuade any of them to meet me. Hence, this article focuses on Doron's case and does not provide details about the other participants. Their apprehension about potential exposure—with its probable concomitant impact on their treatment—stayed with me throughout the writing process. I have therefore also avoided providing identifying details that could unintentionally expose them and I have maintained Doron's confidentiality. For this reason, this article also provides no direct links to publications about either the participants or the company.

Participation in a clinical trial under a regime of (no) hope

I contacted Doron after reading a Facebook post published in Hebrew in 2015 describing his situation. He wrote: 'They took a lot of cells from my body and brought back only some, which means that part of me is still participating in the experiment. I was assured directly by the principal investigator that the company would provide ongoing treatment ...'. This form of writing is unusual in Israeli

society. Most allegations of rights violations in human clinical trial rights are not discussed publicly; cases that do go to litigation tend to be resolved through confidential agreements, limiting the amount of information about such disputes in the public sphere.

We met at Doron's house (Interview, 18 June 2015). From the beginning, he wanted it to be clear that he was not motivated by greed and that he did not seek conflict with anybody. He did not have much time left, he said, and he hoped to spend what he had with his family. He found that the illness had brought him freedom; he did not seek pity and considered himself to be happy. Doron showed me his informed consent form as proof of his contractual rights:

If necessary, according to the principal investigator's recommendation, I may continue receiving the trial product free of charge even after the clinical trial has ended, for a period of three years, if no suitable alternative medical treatment has been found. This is, inter alia, on condition that the product has not yet been approved for use in the requisite indication in a trial in the State of Israel, and cannot be obtained from the HMO/health services in which I am insured. (Informed Consent Form, Art. 8, signed on 19 June 2011)

Doron told me that his decision to take part in the trial was informed by the hope of finding a cure for his condition. He said that he would not have joined the clinical trial without the possibility of it leading to an improvement in his condition. Following the trial, Doron did indeed experience an improvement. This observation was backed up by the medical indices, as reported by the principal investigator on 18 August 2014, at the conclusion of the trial: '... the rate of disease progression dropped from 0.7 degrees per month, to 0.3 degrees per month after treatment, and [...] the muscle and breath function tests had better results'.

There were also contemporaneous media reports regarding the successful outcome of the trial. Doron himself was sceptical about the full veracity of the media coverage, suspecting that it was primarily directed by the relevant parties for economic gain. But the reports did fill him with hope. One published story referred to a patient—an elderly man well known in the Amyotrophic Lateral Sclerosis (ALS) community who had been paralysed by the illness—regaining some physical functioning after the experimental treatment.⁶ Reports also stated that the company directing the trial had begun to trade on the stock market following its success. Investing in a 'regime of hope', as observed by Nik Brown (2015), is part of the infrastructure of new markets and marketing used to promote medical treatments. Publicity concerning the trial's success raised hopes within the ALS community, including among the ALS sufferers who had participated in the trial.

6 This story was widely covered in the media. No references are provided in order to maintain anonymity.

As a result, numerous requests for access to treatment were made to both the hospital and the company, by both participants in the trial and other ALS patients.

Doron, too, requested continued access to the experimental treatment, which he was eligible for under the terms of his informed consent form. His request was supported by a letter of recommendation from the principal investigator on 18 August 2014 and approved by the Ministry of Health (MoH). Doron was certain that he qualified for continued treatment under the terms of the sponsor's statement of commitment (SSC) procedure. However, the company chose to shirk its obligation.

When a clinical trial participant fights to assert his rights

In an attempt to resolve the situation, Doron had a meeting with a representative of the company. According to Doron, the representative told him that the trial treatment had not worked in his case and might even be risky for him, and that this was why the company did not consider itself obligated to continue giving him it. During the meeting, Doron attempted to make sense of the contradictory messages he had received, given what he had seen in the principal investigator's recommendation and in media reports. At this point, Doron reported, 'the conversation become louder and ugly' (Interview, 26 June 2015). The company's representative shouted at him and threw him out of his office, stating that the company was no longer working in Israel.

Doron appealed to the hospital's institutional review board (IRB), asking for its support in exercising his rights. The IRB declined to speak to him on the grounds that his doctor, the principal investigator, was the appropriate person for them to speak to as he represented the interests of the clinical trial participants in discussions with the board.

Doron: Why is there a committee? Isn't it there for me? If there is a case, they should protect me. But they come and say, we don't want to discuss it at all.

Interviewer: Without explaining why?

Doron: [They said] 'If you want us to discuss this, then the doctor should submit a formal request.' I went to the doctor, and he said to me, 'They're fooling you. They sent me an email saying, on the one hand, it's possible, it's done, and on the other hand they don't allow me to prescribe.' All of those things were red flags for me.

Interviewer: I don't understand, who was fooling you?

Doron: I went to the doctor: adult, smart, clever, intelligent, you name it. I'm sitting in front of him, telling him that I took the letter and all and sent it to the

Helsinki Committee (IRB), and I got the answer that they would not help if you don't send a formal request. He pounded the table and said, 'I submitted [it], but they won't let me submit.' In these words. So, what am I supposed to do? I no longer know who's with me and who's against me (Interview, 18 June 2015).

The principal investigator in fact ended up sending two letters to the MoH. The first, which he had sent in August 2014, recommended continuing the trial treatment for Doron using an expanded injection format.⁷ However, in a second letter, which he subsequently sent on 5 May 2015, he changed his proposal and recommended compassionate use.⁸ The principal investigator acknowledged that he had written the second letter after 'discussion on the legal level with the company and hospital'.⁹ In other words, this new letter was the outcome of internal institutional considerations and not necessarily of medical–scientific reasoning. The change in the recommendations apparent in the two letters indicates a transition from a procedure based on the patient's rights (legal rational) to one based on an appeal to goodwill and generosity (social value rational).

The doctor was faced with a conflict between the interests of the participant and those of the institution and the company. This conflict of interests may have been the result of direct pressure on him not only from the company but also from the medical institution (Morin et al. 2002). In Doron's description of his conversation with his doctor, the doctor was helpless, controlled by unnamed forces. Doron believed that the decision was not in the hands of the medical staff; some of the team had maintained contact with him discreetly, encouraging him not to give up. He added that there were 'huge pressures which involve money' (Interview, 18 June 2015).

Participants' rights and protections are heavily dependent on the oversight of IRBs. Under current Israeli regulations, no other social or state body is responsible for protecting the rights of patients in clinical trials; the only other route available to them is direct recourse to the courts. By way of contrast, the US Office for Human Research Protection has a *duty* to protect American clinical trial participants and to set regulations accordingly (Chadwick and Dunn 2000; Burriss and Moss 2006; Stark 2012). It seems that Israel's regulation regime, with the IRB at its centre, does not offer clinical trial participants any real avenues for recourse in the event of complaints or allegations of malpractice. Doron remained alone, with no official body to assert his legal rights.

7 Letter from the principal investigator, 18 August 2014

8 Letter from the principal investigator, May 3 2015.

9 Letter to the head of the MoH clinical trial department, from the investigator-doctor, on compassionate use for the patient, 22 March 2016.

The regulator in the bioeconomy era

As part of Doron's efforts to maintain access to the experimental treatment, he turned to the Ministry of Health (MoH). In its official response, the MoH did show some support for Doron's position, stating that the company and the hospital should approve continuation of the trial treatment as provided for under the contract.¹⁰ This stance notwithstanding, in its role as a regulator the MoH did not apply any pressure on the parties and chose not to impose any sanctions on either the company or the hospital. According to my informant—a Contract Research associate (CRA) worker familiar with the case although not directly involved in it—an MoH official told her that they had tried to speak to the company but to no avail. My informant added that the MoH was under no obligation to act thus and had done so purely out of goodwill (Conversation, 25 Jun 2015).

The MoH legal advisor described the reality in which they were operating:

We have a limitation in enforcing the SCC because it has many qualifications, and it is still difficult to accept the argument of the [pharmaceutical company] that it should not be applied to them. Today, the ability of the MoH to intervene is limited. It is impossible to impose fines because it is not a violation of a law but a breach of contract, which is a contract between the hospital, the company, and the participants. This is why our 'hands are tied' (Interview, 8 June 2016).

According to the legal advisor, the sponsor's statement of commitment (SSC) is at best a matter of contractual obligations; informed consent is anchored in the Patient's Rights Law and can be seen as not just an ethical but also a legal obligation. Because the SSC was part of Doron's informed consent form it therefore constituted a legal obligation. Hence, the regulator had failed in its duty to exercise its power and authority, proving itself unable to protect clinical trial participants from violations of their rights.

Moreover, the MoH claimed that it had no information regarding previous instances of enforcement of entrepreneur contracts of this nature: 'We do not have precise information about the number of cases in which the Ministry of Health had to intervene to ensure continued treatment. There are only a few cases'.¹¹ My broader research project reveals that SSC non-implementation was very familiar to medical staff (Eyal 2018). Interviewees told me that they faced difficulties convincing companies to meet their contractual obligations. In one case, the chairperson of an institutional review board (IRB) for a hospital in Israel (not the hospital involved in Doron's case) described a case in which a company refused

10 OS 16-47979, 18 April 2016, Response by Defendant 3.

11 Response by the MoH Service Division, received under the Freedom of Information Law, 27 April 2017.

to execute the contract, leading to the patient-participant threatening to sue the hospital. In this instance, the patient-participant only changed his mind after being persuaded by the doctor/principal investigator to accept another effective treatment, one that was not experimental. The IRB chairperson remarked that the patient was in the right with respect to his demands, noting that most clinical trial participants were insufficiently aware of their rights as established in the informed consent forms that they signed (Interview, 21 September 2015).

As the regulator, the MoH does not have comprehensive information regarding the clinical trials conducted in medical centres. The relationship between the pharmaceutical industry and the medical centres is conducted with little or no external oversight. The MoH, outside of proceedings and with no crucial influence or authority, lacks the ability to support clinical trial participants in exercising their rights.

The individual versus the collective

Doron and his wife Merav tried to mobilise the other clinical trial participants to unite with them against the other parties. They failed. They found that some of the patients were afraid; others were exhausted as a result of their condition and lacked the strength to take on more struggles. One participant, a young soldier, was granted access to post-trial treatment as a result of intervention by the army (the Israel Defense Forces). Thus, he was not interested in fighting the company because it could pose a risk to his own health. The aggrieved clinical trial participants, each with their own unique and sometimes complex story and facing significant challenges in organising themselves as a group, found themselves isolated—individuals facing the might of the industry.

On top of this, the Amyotrophic Lateral Sclerosis (ALS) community as a group failed to support Doron. It consistently classed Doron's request as falling under the compassionate use criterion. In a 2015 social media post, Dan, the leader of the ALS community commented: 'The patient's demand that the company carry on the trial with him is simply not practical, feasible or relevant, and going out against it is like biting the hand that feeds you'. Doron was aware of these reactions. He said:

Am I a bad person? Explain it to me in a logical way. 'Mr Doron, legally, I am not allowed to give it to you. Mr Doron, technically it is not allowed. Legally, I don't have to or I chose not to give you because its costs me a lot of money' ... If you do not have to, don't give. Had they told me right from the start 'you are going to get only one treatment...' Now, the situation is that some people realise that here comes a man who has been included in the trial, been told that he is going to have one treatment and once it's been helpful to me, I don't

care, I break the rules and want everything for myself (Interview, 18 June 2015).

When Doron said that he did not want any favours or anything that was not his by right, he was sending a message not only to the company but also to his community. Throughout his struggle, Doron tried to convince his community that his fight was not against them and that they shared similar goals. Nevertheless, in an open discussion on Facebook, some observers commented that they should all support the company in its efforts to find a cure and that Doron was trying to bribe the company into treating him; in so doing, he was endangering both the trial and the other patient-participants. Dan, the ALS leader, further observed that 'in order to conduct the orchestra you must first turn your back to the audience'; in other words, he was saying that he was turning his back on Doron and his case because for him, leadership is not about negotiating with your community or directing one's attention toward them but is rather about showing them the way from the front. Another ALS leader told Doron that even if his demands were legitimate, they nevertheless could not go against the company.

Nikolas Rose and Carlos Novas (2004, 24) have discussed the growing influence of patient organisations and their political activism in the world of science. Novas (2006) stressed the efforts made by these groups, as patient advocates, to promote the development of cures or treatments without, however, undermining the free market—a stance that reflects their positioning in the wider bioeconomy. The longing for a cure promotes a 'political economy of hope' (DelVecchio Good et al. 1990; Novas 2006; DelVecchio Good 2007) that mobilises patients and their advocates to side with market interests, even when the market interest in question infringes on the rights of the individual.

The National Bioethics Committee discussed the ALS clinical trial case with representatives of Israel's pharmaceutical industry, the ALS support organisation, the ALS principal investigator, and officials from the Ministry of Health (MoH). At the meeting, none of the parties—including the ALS support organisation—referred to Doron's case and his argument for it to be considered as a sponsor's statement of commitment (SCC). Therefore, the issue of failing to fulfil the requirements of the agreement as outlined in the informed consent form was not put before the Committee (Interview with a member of the National Bioethics Committee, 2 February 2015). Their focus was instead on 'compassionate use' guidelines and industry involvement; thus, the starting point for their discussion was the same as that for the company and the hospital. By concentrating on the compassion discourse, the arena becomes characterised by the framework of social value rationality; as such, the industry, which is the source of the compassion here, becomes a legitimate social actor. Conversely, focusing on the

legal discourse would probably have framed the industry as lawbreakers or uncooperative.

The position of the ALS organisation recalls that of the hospital, situated as it was between the patients and the industry. The organisation saw the biotech company behind the clinical trials as a compassionate potential saviour in need of the organisation's support to continue its medical–scientific work. In other words, the ALS support organisation adopted the company's perspective, aligning itself with the hospital by doing so. Doron, for his part, felt that he was being pushed into proving his loyalty to his community and his commitment to the collective good. Thus, he was left alone in the battle for his rights, marked out by the company, the hospital, and his own community as a lone agent seeking to sabotage the medical–scientific project of finding a cure available to all.

In the court: Justice versus science

In 2016, Doron filed a suit in the magistrate's court against three respondents: the medical institution, the company, and the Ministry of Health (MoH)—the last because of its legally mandated regulatory role over clinical trials. In their initial statement, the company, sponsors of the clinical trial stated the following:

Defendant 2 [the company] has no direct contact with the patients, who were recruited to the trial and treated by the hospital [...]. The information about the trial, including the patients' signing of informed consent forms, was given to the patients by the officials responsible for the trial in the hospital, and they are the ones who maintained regular contact with the patients (Opening Statement (OS) 16-47979, 18 April 2016, Response by Defendant 2, Art. 8).

According to the company, then, it was not involved in or party to the relationship with the patients and therefore had no obligation toward them. It should be noted that in the case of a clinical trial, a contractual relationship exists between the medical institution and the company that includes sponsorship obligations relating to the trial's set-up. Hence, even if the company did not have a direct relationship with the patients—a separation enforced for ethical and medical reasons—it is not absolved of responsibility for them.

The medical institution chose to support the company's argument. In its originating summons, it argued:

No delegate or responsible official on behalf of the [the company] presented, said or noted to [the plaintiff] that 'in that case the treatment proves to be safe and effective, he may continue to receive the trial product even after the end of the clinical trial' (OS 16-47979, 18 April 2016, Response by the Hospital, Art. 39).

The medical institution was responsible for approving all aspects of the clinical trial, including the informed consent procedure. However, the hospital rejected what was recorded in—and therefore required by—the informed consent form. Instead, it supported the company. This reflects the nature and imbalance not just of the doctor-investigator and patient-participant relationship but also that of the medical institutions and the pharmaceutical industry. In Israel, as elsewhere, the pharmaceutical industry is a major source of funding for clinical trials. It underwrites more than half of the clinical trials conducted in government hospitals (Israel Central Bureau of Statistics 2014). In some medical institutions, 70% of all clinical trials are funded by the industry. In 2014, the pharmaceutical industry invested a total of 470 million NIS (Israeli new shekels, 146.7 million USD) in clinical trials.¹² In this sense, the industry is an important source of income for medical institutions and is thus able to wield considerable influence over them (Goldacre 2013; Eyal 2018). The company and the hospital were both working not only to exclude Doron from arenas in which he could exercise his rights but also to mark these arenas as off-limits to him or as places where any claim to a specific contractual right was irrelevant or unrelated to them. By doing so, they sought to deprive the patient of his power and, as a corollary, of his rights.

In the court, the hospital and the company advanced two main arguments. First, they argued that the research product had been modified.¹³ Consequently, they claimed, Doron was asking for access to a different product from that referred to in his informed consent document—a product with a different indication and means of administration. In support of this argument, they referred to the doctor's second letter, sent two years after his first, recommending integrated therapy. However, according to the MoH, while changes had been made to the product and its administration, the therapeutic principles remained the same and thus warranted consideration under the SSC.¹⁴ The MoH asserted that the distinctions being made by the hospital and the company could harm Doron's rights.

The biomedical system is governed by the economic–industrial model. Bioeconomic considerations are an incentive for minimising patient rights according to market needs and norms—economic considerations that override the wellbeing, rights, and interests of participants in clinical trials (Petryna 2005). The company concluded that Doron's request ought to be considered under the rubric of compassionate use; by doing so, it sought to reposition the discussion in a social domain (compassion) rather than a legal or legislative one.

12 Ministry of Health Committee on Commercial Contracts, Approvals by the Committee on Contracts with Commercial Firms – Summary of 2014 and Comparison with 2012–2013, April 2016 (Hebrew). See: <https://www.health.gov.il/>.

13 OS 47939-02-16, 18 April 2016, Response by the Hospital.

14 OS 47939-02-16, 18 April 2016, Response by the MoH, Art. 23.

The second argument dealt with the concept of medical authority as being exclusive to the scientific–medical realm, thereby excluding external and unscientific considerations. In the company’s words: ‘This is purely professional medical discretion, which is not a matter for court discussion’.¹⁵ The hospital responded in a similar vein:

[A] ruling that exposes research investigators to judicial review of a decision to give repeated treatments at a very high cost will greatly impair the conduct of these experiments (Art. 22). Moreover, an experiment in which patients who have participated can receive additional treatment based on *judicial* discretion would be a *biased* experiment—one whose findings are unclear.

These arguments, advanced by the defendants collectively, played a significant role in overcoming any ethical, legal, or regulatory contentions. The company is part of the scientific medical establishment, an ally with overlapping interests. The court, for its part, is external to science and therefore not necessarily competent to make judgments on professional decisions largely based on scientific considerations. This rationale operates in two ways simultaneously: at once reducing the legal and ethical validity of the rights of the trial participants and increasing the power of the pharmaceutical industry and the hospital.

In court, the company and the hospital sought to frame the discussion as one related to the discretion afforded by compassionate use rather than one of inherent rights. After listening briefly to both sides, the judge asked them to step outside and try to reach a negotiated agreement ‘for everyone’s benefit’.¹⁶ There, in the corridor, Doron (in a wheelchair) and his wife stood to one side as, two metres away from them, Doron’s lawyer discussed the case with three lawyers from the hospital, the company’s lawyer, and the MoH’s legal advisor. They agreed to continue the discussion away from the court. A few weeks later, I spoke with Doron and his wife. They said that an agreement had been reached to provide one more injection, as had been proposed by the company from the start. Doron accepted this, but before the necessary approvals came through he contracted pneumonia and decided to opt out of the treatment.

Joao Biehl and Adriana Petryna (2013; Biehl 2013) have explored how right-to-health litigation has become an alternative pathway for Brazilians to access healthcare. According to these authors, the rights discourse is channelled through the courts, which then become a site of biopolitical management. In the case of Israel, the courts tend to avoid full engagement. Doron’s case emphasises the fact that bioeconomic considerations are part of the economic and scientific apparatus,

15 OS 47939-02-16, 18 April 2016, Response by the Hospital, Art. 16, quote from Tel Aviv District Court, *A.S. v. State of Israel-MoH* (Nevo, 12 January 2010).

16 Observation at Tel Aviv District Court, 18 April 2016.

separated from the litigation pathway as two different rationales: scientific versus rights.

Concluding remarks

Doron's case draws out the parallels, and sometimes the ambiguity, between compassion and health rights. Moreover, it prompts questions concerning tensions between the biomedical industry and healthcare, individuals (the patient) and collectives (the Amyotrophic Lateral Sclerosis or ALS community). Confronted with these tensions, the patient must defend their rights against competing discourses advanced by the industry and the illness community. In this respect, this case reveals the broader context of constructed and contested social values, with both economic and medical actors seeking to expand or narrow them according to their vested interests.

The terms 'legal rights' and 'compassion' derive their power and legitimacy from essentially different content worlds. The right to health, which includes the right to treatment, information, and access is established through economic, political, cultural, and normative interests. The relationship between these variables and interests can affect the nature of the power dynamics that unfold in the clinical trials arena (Petryna 2009; Lock and Nguyen 2011; Biehl and Petryna 2013). The patient's position will be defined accordingly—rights holder or object of pity; passive or active; participant or subject (see, e.g., Corrigan and Tutton 2004)—not only terminologically but also as an aspect of broader social and institutional perceptions and rationales. Didier Fassin (2005, 2011), referring to immigrant policy, argued that the 'right to life' has been displaced from the political rationale of the state by the notion of compassion for the suffering body. Similarly, the term 'biolegitimacy' (Fassin 2005) has been used to describe the process of securing one's legitimate rights as a sufferer of a life-threatening disease, over and above the social and economic rights. 'Biolegitimacy' relates to the rationale of the state in legitimising the rights of non-citizens. In Doron's case, however, where citizens are entitled to these rights, the suffering body has been deprived of otherwise legitimate rights and is subject instead to the notion of compassion. The process of legitimacy is directed by the industry's interests (social and economic) at the expense of the rights of the patients.

Compassion is a social value, signifying not only the person who deserves compassion but also the person who is being compassionate. In this way, in the arena of clinical trials the pharmaceutical industry is able to establish the legitimacy of its social position within the rationale of social values, drawing on its positioning as a moral–social institution. The company becomes an agent of social improvement, or a 'good corporate citizen' (Rajak 2011, 68). Central to this framing

are the attendant corporate and economic values and the unresolved duality of 'market' and 'value'—all evoked in pursuit of market rationalism. In the ALS case, compassion has two roles. First, it enables the company to be perceived as a virtuous social actor; second, it takes the place of the rights of the patients, whereby economic interests determine when and how each right is to be fulfilled. Rights become subject to the market order via the purported social virtues of the industry.

Under the bioeconomy of value, the industry gets to define compassion as goodwill. 'Israel Pharma', the association of Israeli pharmaceutical companies, defines compassion as 'funding treatments for populations unable to afford them, for charities, patients' organizations, and medical assistance organizations' (Pharma Israel 2014, 3). According to its report, under the compassionate use clause the industry has provided treatments at an estimated annual cost of 15 million NIS (4.7 million US dollars). In the case discussed here, the company stated this in its response: 'As for compassionate use, not only is there no obligation on behalf of the clinical trial initiator—in this case the company—by the power of law to provide requested compassionate use, but the treatment is not defined or even sought in the action'.¹⁷ The company uses social terminology to locate itself as part of society and scientific interests; in doing so, it defines its role as a decision-making authority with regard to science and social rights, as well as with regard to Doron's status.

It would seem that treatment provided under the definition of 'compassion' *could* give Doron what he so badly needed. But he wanted to actualise his *legal* rights, not be forced to rely on a narrow conception of charity, not receive treatment unfairly, and not advance his personal interests at the expense of the collective as had been suggested by his illness community.

The choice to define the treatment in terms of rights or in terms of compassion can in fact be conceived as a choice between something established by law and designed to protect the individual and his autonomy, or a value-based framework designated as goodwill and with no binding obligation. The act of compassion, as encapsulated by the term 'compassionate use', has replaced the acts of enforcing rights and fulfilling contractual obligations. Doron's struggle against the company in the absence of support (regulatory, judicial, or communal) was doomed to fail.

These two axes—right vs. value and individual vs. collective—are not separate. They are intertwined and create the cultural means of negotiating social and economic imperatives for health, economy, and rights in contemporary society. In the first, we see how compassion, through economic interests, becomes part of

17 OS 16-4749, 18 April 2016, Response by the Entrepreneur, Art. 13.

the medical and social system or collective, pushing aside the individual and their rights. In the second, we see that collectives can work in the name of justice and compassion while at the same time excluding the individual, who can no longer argue for the enforcement of a specific right. As a result, the production of both, rights and health, are bound up with economic values.

To conclude, this article traces Doron's case and his attempts to implement the rights established by his signing of an informed consent form; rights, in fact, created on the day he agreed to participate in the clinical trial. The biotech company and the hospital argued that this was not a case of contractual rights but rather one of discretion afforded by the notion of granting 'compassionate use'. I have examined the considerations and contested meanings of right and value, and their meanings for participants in clinical trials. The centrality of the biomedical industry in the medical system made it possible for it to deny a patient their legal right and to offer compassion instead. Such compassionate acts are designed to preserve a hierarchy that deprives the patient of their power and their rights. Simultaneously, the biotech industry emphasises its power as moral partner and a 'saviour' in its relationship with patient organisations, and as a medical–scientific actor in the medical system.

Acknowledgements

I thank Dr. Adi Moreno, Dr. Ruth Presser, and the journal's anonymous reviewers for their thoughtful comments.

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