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SCHOLARLY ARTICLE

Leveraging Human Rights Due Diligence in Corporate-State Procurement: The Exemplar of the Pfizer-Israeli COVID-19 Vaccination Program

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Abstract

This article opines that corporations should utilize leverage in procurement contracts with states to prevent human rights abuses. Capitalizing on leverage over state business partners should be understood as an under-explored but intriguing dimension to the advancement of human rights. This article uses the example of the Pfizer-Israel procurement contract to provide mRNA COVID-19 vaccinations as a case study. While the Pfizer-Israel contract required Israeli governmental compliance with various laws, and referenced other legal obligations, no reference to human rights, such as the right to informed consent, was referenced in any contractual provision. The failure of Pfizer to insert contractual provisions regarding the Israeli government's duty to obtain informed consent provides a glaring exemplar of a missed corporate opportunity to fulfil the corporate responsibility to respect human rights.

Keywords: Corporate leverage; Due diligence; Human rights; Informed consent; Vaccine

> [P]rocurement can be understood as an umbrella for privatized governmental services as well as a set of economic transactions for the provisions of goods and services necessary for the internal operation of the state itself. States, thus, can use procurement as a means of providing appropriate models for contractual provisions sensitive to human rights issues that might influence private sector business behaviors as well.[1]

I. Introduction

Corporate responsibility for human rights abuses has become an increasingly important focus of international law.[2] Initially understood as state responsibility to monitor

[1] Larry Catá Backer, 'Moving Forward the UN Guiding Principles for Business and Human Rights: Between Enterprise Social Norm, State Domestic Legal Orders, and the Treaty Law that Might Bind Them All' (2015) 38 *Fordham International Law Journal* 457, 483; Olga Martin-Ortega, 'Public Procurement as a Tool for the Protection and Promotion of Human Rights: A Study of Collaboration, Due Diligence and Leverage in the Electronics Industry' (2018) 3:1 *Business Human Rights Journal* 75, 76 ('Public [government] procurement offers a potentially valuable contribution to the search for strategies to improve human rights in global supply chains.'). However, the opposite is also true: corporations can leverage contractual provisions to influence states to comport with human rights obligations.

[2] Surya Deva, 'Business and Human Rights: Alternative Approaches to Transnational Regulation' (2021) 17 *Annual Review of Law and Social Science* 139.

corporations, the conceptual framework has undergone an expansion in recent years to encompass independent corporate responsibilities.[3] Particularly significant, the United Nations Guiding Principles on Business and Human Rights (UNGPs) tasks states with protecting, and businesses with respecting, human rights.[4] The UNGPs reference a business responsibility to perform human rights due diligence (HRDD) on business partners – including state-linked entities – to respect human rights in connection with the contract's performance.[5]

The business responsibility to undertake HRDD has generally been conceptualized as due diligence over subsidiaries and supply chain partners.[6] Given corporate leverage over such entities, utilizing leverage has been increasingly recognized as an important tool to promote human rights.[7] However, an under-explored pathway to advance human rights is the corporate responsibility to capitalize on leverage with state business partners. Focusing on corporate responsibilities regarding state procurement contracts is important for several compelling reasons. First, states are often contract parties in commercial relationships and these partnerships or collaborations are likely to increase in the future.[8] Second, global corporations are powerful actors with economic leverage and human rights compliance language can be inserted into commercial arrangements with States.[9] Third, large corporations have extensive expertise in international law and can use this expertise to enhance both awareness and compliance with human rights responsibilities.[10] Fourth, states might have a conflict of interest – either economic or political – with citizens and HRDD might be particularly important when a business partner is a potentially problematic government.[11]

This article explores the corporate responsibility to respect human rights in the context of the Pfizer-Israel COVID-19 vaccine procurement and collaboration. Self-described as a 'collaborative evidence collaboration agreement', the article raises the question whether

[3] Surya Deva, 'Treaty Tantrums: Past, Present and Future of a Business and Human Rights Treaty' (2022) 40:3 *Netherlands Quarterly of Human Rights* 211.

[4] Human Rights Council, 'Guiding Principles on Business and Human Rights: Implementing the United Nations "Protect, Respect and Remedy" Framework', A/HRC/17/31 (21 March 2011). Principle 5 provides that 'States should exercise adequate oversight in order to meet their international human rights obligations when they contract with, or legislate for, business enterprises to provide services that may impact upon the enjoyment of human rights.'.

[5] See Section IV.

[6] Rachel Chambers, 'Parent Company Direct Liability for Overseas Human Rights Violations: Lessons from the UK Supreme Court' (2021) 42 *University of Pennsylvania International Law Journal* 519, 527. See also Rob Davies, 'The Guardian, BAT and Imperial Tobacco Firms Profited from Child Labour, Law Firm Alleges' (18 December 2020), https://www.theguardian.com/business/2020/dec/18/bat-imperial-tobacco-firms-child-labour-law-firm-alleges (accessed 24 April 2023); European Centre for Constitutional and Human Rights, 'KiK: Paying the Price for Clothing Produced in South Asia', https://www.ecchr.eu/en/case/kik-paying-the-price-for-clothing-production-in-south-asia/ (accessed 24 April 2023).

[7] Florian Wettstein, 'Betting on the Wrong (Trojan) Horse: CSR and the Implementation of the UN Guiding Principles on Business and Human rights' (2021) 6:2 *Business and Human Rights Journal* 312, 315 ('a number of countries have already adopted legislation containing human rights due diligence obligations in recent years').

[8] Amel Karboul, Emily Gustafsson and Max McCabe, 'Partnerships for Public Purpose: The New PPPs for Fighting the Biggest Crises of Our Time' (27 May 2021), https://www.brookings.edu/blog/education-plus-development/2021/05/27/partnerships-for-public-purpose-the-new-ppps-for-fighting-the-biggest-crises-of-our-time/ (accessed 24 April 2023).

[9] Larry Catá Backer, 'The Emerging Normative Structures of Transnational Law: Non-State Enterprises in Polycentric Asymmetric Global Orders' (2016) 31 *Brigham Young University Journal of Public Law* 1, 50 ('States and corporations are now capable of deploying forces in the field – sometimes states hire corporations that serve as mercenary armies that protect its own operations as well as those of the institutions of the state from sub-national and supra-state threats.').

[10] Rachel Brewster and Philip J Stern, 'Introduction to the Proceedings of the Seminar on Corporations and International Law' (2018) 28 *Duke Journal of Comparative and International Law* 413, 420.

[11] Chambers, note 6.

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Pfizer had a responsibility to engage in due diligence to prevent human rights abuses by ensconcing into the Pfizer-Israel contract the Israeli government's obligation to obtain informed consent from Israeli citizens.[12] The issue of informed consent during a pandemic is crucial as the failure to safeguard human rights is a slippery slope which might result in additional serious violations of human rights beyond informed consent.[13]

This article contributes to the literature by arguing that corporate leverage on states is potentially an effective mechanism to address human rights concerns and proceeds as follows. Section II discusses the Pfizer-Israel collaboration to vaccinate Israelis with Pfizer's mRNA COVID-19 vaccine. Section III focuses on the right to informed consent and the state duty to ensure informed consent was obtained. Section IV analyses how a corporation can fulfil its responsibility to respect human rights by capitalizing on leverage with state partners. Section V provides concluding observations.

II. The Pfizer-Israel Government 'Project' and Marketing Campaign to Vaccinate Israelis

This section describes the Pfizer-Israel procurement and data sharing collaboration contract. It begins with a description of the contract (redacted in the publicly available version) and the Israeli government's campaign to promote vaccination.

The Pfizer-Israel Partnership: The Israeli Government's Procurement Contract and Collaboration Agreement

The COVID-19 global pandemic swept the globe in early 2020, incentivizing expedited development of vaccines such as Pfizer's mRNA vaccine. In or around December 2020, the Israeli government entered into a procurement contract ('Pfizer-Israel Contract' or 'Contract'), titled 'Epidemiological Evidence Collaboration Agreement' (referred to in the Contract as 'the Project'), for the supply of Pfizer's mRNA vaccines to Israel as well as comprehensive data sharing. According to Pfizer's chief executive officer (CEO) Bourla, he and Prime Minister Netanyahu had thirty discussions prior to signing the Contract.[14]

The Israeli government initially refused to publish the Contract, insisting on complete secrecy. Israeli officials claimed disclosing the contents of the Pfizer-Israel Contract would be criminal: 'In November [2020], at a cabinet meeting, Health Ministry Yuli Edelstein said that the release of details of contract with Pfizer would be "criminal". Prime Minister Netanyahu then added that "there are sections that cannot be disclosed" and that the supply of the vaccine should not be endangered'.[15]

Eventually, immense media and public pressure led the Israeli government to reluctantly publish a heavily redacted version of the Contract which was subsequently removed without

[12] This approach comports with the UNGPs which emphasize the need for businesses to perform HRDD with respect to business partners, including state-linked businesses. See Section IV.

[13] Eric Richardson and Colleen Devine, 'Emergencies End Eventually: How to Better Analyze Human Rights Restrictions Sparked by the COVID-19 Pandemic Under the International Covenant on Civil and Political Rights' (2020) 42 *Michigan Journal of International Law* 105, 108 ('well-meaning but poorly considered restrictions in the name of combatting COVID-19 threaten to undermine hard-won human rights protections and may, in fact, erode important elements of IHRL as a result of overreaching implementation').

[14] As Pfizer is the party that signed the Contract with the Israeli government, it is referred to as the Pfizer-Israel Contract. See 'Pfizer CEO Hails "Obsessive" Netanyahu for Calling 30 times to Seal Vaccine Deal' (11 March 2021), https://www.timesofisrael.com/pfizer-ceo-obsessive-netanyahu-called-30-times-in-effort-to-seal-vaccine-deal/ (accessed 24 April 2023).

[15] Ido Efrati, 'Israel Reveals the Patients' Data It Gives Pfizer as Part of COVID Vaccine Deal' (19 January 2021), https://www.haaretz.com/israel-news/israel-reveals-what-patient-s-data-it-gives-pfizer-as-part-of-covid-vaccine-deal-1.9459439 (accessed 24 April 2023).

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explanation from the Ministry of Health website but is available on non-governmental websites.[16] Entire contractual provisions related to indemnification, damages and liability, along with isolated sentences, are completely blacked-out in the version made public,[17] as are the provisions on dispute resolution.[18] While there was no profit sharing,[19] the Pfizer-Israel Contract obligated Israel to transfer an exhaustive amount of data to Pfizer,[20] and both parties 'agreed to cooperate on a reasonable basis to share information ... including to track its benefits'.[21]

The Israeli government seemingly assured Pfizer that it would endeavour to use the Pfizer vaccine on all Israeli citizens.[22] Corroborating Pfizer's understanding is the statement of the Israeli Prime Minister Netanyahu: 'The agreement with Pfizer will see all Israeli citizens above the age of 16 vaccinated by the end of March in a campaign called "Back to Life" ... We agreed that Israel will be a model for the world for the vaccination of an entire country'.[23]

As discussed below, the campaign was vigorous and indeed endeavoured to have all citizens vaccinated.

The Israeli Government's Efforts at Vaccinating All Israelis

The campaign to vaccinate was ensconced in governmental claims to the Israeli public that the United States' Food and Drug Administration (FDA) had definitively found the vaccine safe with no side-effects. For example, to convince Israeli citizens of the vaccine's complete safety,[24] the Israeli government and Health Maintenance Organizations (HMOs) commenced marketing the vaccine as safe and effective. In one example, an advertisement featured the Israeli Prime Minister mocking anyone questioning the safety of the Pfizer mRNA vaccine describing those asking questions as 'clowns' and claiming the Pfizer vaccine had already been 'approved by the Americans'.[25]

However, when the Israeli vaccination program commenced, the FDA had only provided for an Emergency Use Approval (EUA) pending further testing. An EUA is fundamentally different from full approval, and is based on a reasonable belief of effectiveness and a dearth

[16] See 'Epidemiological Evidence Collaboration Agreement', https://www.keionline.org/misc-docs/IsraelMOH-Pfizer-Collaboration-Agreement-6Jan2021.pdf (accessed 1 August 2023).

[17] Several portions are partially redacted while some are completely redacted; ibid.

[18] Ibid. Section 10.10 on dispute resolution is redacted in its entirety.

[19] Ibid. Section 10.1 provides: 'Pfizer and MoH acknowledge and agree that nothing herein contained is intended to constitute them as employer/employee, joint ventures or partners, it being their intention that each Party shall have an independent relationship with the other Party'.

[20] Ibid, Exhibits A and B. See also Shira Rubin and Steve Hendrix, 'Israel Moves to Head of Vaccine Queue, Pffering Pfizer Access to Country's Health-care Database' (28 January 2021), https://www.washingtonpost.com/world/middle_east/israel-pfizer-coronavirus-vaccine-privacy/2021/01/27/b9773c80-5f4d-11eb-a177-7765f29a9524_story.html (accessed 24 April 2023).

[21] 'Epidemiological Evidence Collaboration Agreement', note 16.

[22] 'Israel Set to be First Country to Vaccinate Entire Population Against COVID-19' (20 January 2021), https://www.europeanpharmaceuticalreview.com/news/140293/israel-set-to-be-first-country-to-vaccinate-entire-population-against-covid-19/ (accessed 24 April 2023).

[23] Danny Zaken, 'Netanyahu: All Israelis Will Be Vaccinated by March' (7 January 2021), https://en.globes.co.il/en/article-netanyahu-all-israelis-will-be-vaccinated-by-march-1001356428 (accessed 24 April 2023).

[24] While it is true that the Pfizer vaccine had already been approved by the FDA for emergency use, it is a question of fact whether the Israeli public was aware of the distinction between FDA approval for adult emergency use and full FDA general approval, or the fact full FDA approval was pending and would depend on data from the initial roll-out.

[25] See https://www.youtube.com/watch?v=0hS9TEDULgs (accessed 24 April 2023) (at second 19) claiming the vaccine was 'FDA approved' and calling anyone questioning the vaccine 'a clown'.

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of information regarding risks exist.[26] Accordingly, due to the unique circumstances associated with an EUA, the FDA provides a Fact Sheet for EUA-approved products to ensure recipients are informed of the risks:

> FDA must ensure that recipients of the vaccine under an EUA are informed, to the extent practicable given the applicable circumstances, that FDA has authorized the emergency use of the vaccine, of the known and potential benefits and risks, the extent to which such benefits and risks are unknown, that they have the option to accept or refuse the vaccine, and of any available alternatives to the product. Typically, this information is communicated in a patient 'fact sheet'. The FDA posts these fact sheets on our website.[27]

Indeed, the first FDA Fact Sheet explicitly advised, 'adverse effects are unknown and the vaccine remains in clinical trials'.[28]

Yet, the FDA Fact Sheet was not provided to the Israeli vaccine recipients in either Hebrew or English. Moreover, the intensive Israeli governmental marketing campaign failed to disclose that the FDA approval was an EUA and that the vaccine was still undergoing testing. Indeed, the Israeli vaccination drive was part of the testing and constituted a 'sort of a "Phase 4" study'.[29] These facts were neither noted in the marketing efforts nor widely communicated (if at all). Based upon the author's conversations with hundreds of Israeli Pfizer vaccine-takers, including university students who were vaccinated in widely diverse locations throughout Israel, and adults working in various sectors, no written information and no disclosure was provided at the Israeli vaccination centres informing recipients that the FDA had only issued an EUA approval.[30]

In a further exemplar of the failure to fully disclose, Israel's HMOs emphasized only the positive, stating that Pfizer's mRNA vaccines were safe and the 'only way' to return to normal life: 'The vaccination has undergone intensive testing phases, and health officials both in Israel and worldwide have determined that *the vaccine is safe for use....* Operation "Vaccinating for Life" *is the only way that will allow us to resume our normal lives*'.[31]

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[26] See 'FDA EUA Approval for the Pfizer COVID-19 mRNA Vaccine', https://www.fda.gov/news-events/press-announcements/fda-takes-key-action-fight-against-covid-19-issuing-emergency-use-authorization-first-covid-19 (accessed 24 April 2023). EUA is different from full approval. See 'Understanding the Regulatory Terminology of Potential Preventative and Therapeutic Drugs for COVID-19', https://www.fda.gov/consumers/consumer-updates/understanding-regulatory-terminology-potential-preventative-and-therapeutic-drugs-covid-19#:~:text=The%20process%20for%20issuing%20an,needed%20for%20an%20FDA%20approval (accessed 24 April 2023). Full approval means the FDA determined the clinical data demonstrates efficacy and safety. In contrast, the 'process for issuing an EUA is different than an FDA approval. Under an EUA, the FDA authorizes uses of medical products based on a reasonable belief that the product may be effective based on the best evidence available at the time, without waiting for all the information that would be needed for an FDA approval'.

[27] 'Emergency Use Authorization for Vaccines Explained', https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained (accessed 24 April 2023).

[28] 'Fact Sheet for Recipients and Caregivers' Authorizations of Emergency Use of Two Biological Products During the COVID-19 Pandemic', https://www.federalregister.gov/documents/2021/01/19/2021-01022/authorizations-of-emergency-use-of-two-biological-products-during-the-covid-19-pandemic-availability (accessed 24 April 2023).

[29] See David Gurwitz, 'COVID-19 *Vaccine* Hesitancy: Lessons from Israel' (2021) 39 *Vaccine* 3785. Phase IV trials collect additional data about the safety and efficacy of the product but clinical Phase IV trials have the same ethical requirements as Phase I–III trials with respect to informed consent. See Rosemarie DC Bernabe et al, 'Informed Consent and Phase IV Non-Interventional Drug Research' (2011) 27:3 *Current Medical Research and Opinion* 513–518.

[30] Based on the author's discussions with hundreds of vaccinated Israeli students from all over Israel between 2021 and 2023, as well as dozens of friends and neighbours, no information at all was provided, nor were any questions asked about recipients' health conditions.

[31] See 'The Corona Virus Vaccination – Information', https://www.leumit.co.il/eng/Life/FamilyHealth/familyhealth/coronavirus/articlegalleryitem,5171/ (accessed 24 April 2023) (emphasis added). Alternative

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Furthermore, public messages and announcements from some Israeli government officials were highly critical of individuals who did not want to take part in 'the Project'.[32] The officials claimed that the vaccine 'hold-outs' were delaying a full re-opening of the economy[33] and strongly implied that those unvaccinated would suffer consequences such as losing rights and potentially employment.[34] The public perceived that the government was providing a 'green-light' to terminate unvaccinated employees.[35]

As noted by a Professor Emeritus of Tel Aviv University's Medical School, Israelis were hesitant but substantial pressure was imposed on citizens to be vaccinated.[36] For example, the Israeli government advanced legislative proposals (eventually defeated) allowing the Israeli social services (Welfare Department) and other governmental agencies to ascertain the identities of the unvaccinated with the intention of contacting parents and asking why their family was not vaccinated.[37]

Receiving a call from the Israeli social services department – which has been heavily criticized for aggressively removing children from homes based solely on anonymous abuse reports – asking why parents have not been vaccinated (or vaccinated their children) which governmental agencies could interpret as child abuse would place immense pressure on parents to vaccinate minors.[38]

Illustrating the ambition to have every Israeli citizen vaccinated,[39] the Israeli government recommended the vaccination of pregnant women[40] as well as aggressively promoting vaccinating minors[41] notwithstanding the fact that when the Israeli government

vaccines such as non-mRNA and/or Chinese vaccines as well as natural immunity were never mentioned as potential alternatives in these marketing efforts.

[32] 'Anyone unwilling or unable to get the jabs that confer immunity will be "left behind", said Health Minister Yuli Edelstein'. Laurie Kellman, 'Vaccination "Passports" May Open Society, but Inequity Looms' (26 February 2021), https://apnews.com/article/coronavirus-vaccination-passports-7a8ce11ce37c309d97969ab71df26e62 (accessed 24 April 2023). See also Isabel Kershner, 'As Israel Reopens, Whoever Does Not Get Vaccinated Will Be Left Behind' (18 February 2021), https://www.nytimes.com/2021/02/18/world/middleeast/israel-covid-vaccine-reopen.html (accessed 24 April 2023) (noting pressure on citizens to take the Pfizer vaccine and the governmental implicit warning that refusing to be vaccinated will bring economic hardship to the 'hold-outs'). See also Winer, note 34.

[33] As the Israeli economy had essentially fully reopened by April 2021 notwithstanding the fact that many Israelis remaining unvaccinated, the claim that 'hold-outs' were responsible for not re-opening the economy was not accurate.

[34] Stuart Winer, 'Edelstein Mulls Bill to Enable Employers to Ban Non-Vaccinated Workers' (10 March 2021), https://www.timesofisrael.com/edelstein-mulling-bill-to-enable-employers-to-ban-non-vaccinated-workers/ (accessed 24 April 2023).

[35] 'Israel's Unvaccinated Fear Exclusion' (26 February 2021), https://www.yahoo.com/news/israels-unvaccinated-fear-exclusion-152649526.html (accessed 24 April 2023)

[36] 'Actions that discriminate against vaccine hesitant or resistant individuals constitute a risky 'slippery slope' toward further human rights violations, while their effectiveness is questionable', Gurwitz, note 29.

[37] 'The law allows city workers to use the information to contact those people and try to convince them to do so. The measure also grants the education and welfare ministries access to that information.' Dina Kraft, 'Israel Turns to Carrots, and Maybe Some Sticks, to Persuade COVID-19 Vaccine Holdouts' (26 February 2021), https://news.yahoo.com/israel-turns-carrots-maybe-sticks-165838959.html (accessed 24 April 2023).

[38] Naama Lansky and Michal Yaakov Yitzchaki, 'Where is My Child?' (20 December 2013), https://www.israelhayom.co.il/article/142317 (accessed 24 April 2023) (increasing scrutiny over the Israeli welfare department policy of removal of children from homes based on anonymous reports and overly-zealous social workers).

[39] See https://govextra.gov.il/ministry-of-health/covid19-vaccine/home?gclid=CjwKCAiAm-2BBhANEiwAe7eyFBNXQQUKsfZUX1lB7kpRp4x4GXZ0gHpBURzlgA1pasBDMbV66L8VcxoCwkYQAvD_BwE (accessed 24 April 2023).

[40] See https://govextra.gov.il/media/30093/pregnancy-covid19-vaccine.pdf (accessed 24 April 2023).

[41] Tzvi Joffre, 'At-Risk Children Received COVID Vaccine Despite Lack of Data' (4 February 2021), https://www.jpost.com/israel-news/at-risk-children-received-covid-vaccine-despite-lack-of-data-report-656851 (accessed 24 April 2023).

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did so, the World Health Organization (WHO) had stated on 8 January 2021, 'due to insufficient data, WHO does not recommend the vaccination of pregnant women at this time'.[42] While WHO ultimately retracted its advice later, at the time the vaccination campaign was rolled out in Israel, WHO had advised against vaccinating pregnant women. Moreover, similarly with respect to children, on 8 January 2021, WHO stated that it was not recommended to vaccinate children less than 16 within a high-risk group.[43] Notwithstanding this advice, the Israeli government pushed to vaccinate children less than 16.[44] Media campaigns and repeated telephone calls and text messages from Israeli HMOs urged parents to vaccinate everyone in the family.

The next section discusses the obligation of states to obtain informed consent and analyses whether the Israeli government complied with this international legal norm.

III. Did the Israeli Government Have a Duty to Obtain Informed Consent and Fail to Fulfil the Obligation?

This section discusses the state obligation to ensure informed consent was obtained and raises the question whether the Israeli Government failed to comply with obtaining informed consent. Informed consent is considered a vital international legal obligation and the failure to obtain consent is considered abhorrent.[45] In the context of medical experimentation, informed consent is among the rights of the highest magnitude of importance, a *jus cogens* norm, and therefore no state can abrogate these obligations.[46]

The Duty to Obtain Informed Consent

Informed consent is fundamental to human rights, and is specifically articulated in the International Covenant on Civil and Political Rights (ICCPR).[47] The ICCPR, which is addressed to state actors, established informed consent for medical experimentation as a critical human right and *jus cogens* principle of international law.[48] As described above, at the time of the vaccination program the Pfizer mRNA vaccine had only received an EUA approval and likely constituted a Phase 4 trial. Furthermore, considering Pfizer CEO Bourla's explicit reference to Israel serving as a 'world laboratory', it is quite reasonable to conclude the 'Project' was indeed a medical experiment. Accordingly, it is manifestly clear that the Israeli government was obligated to obtain informed consent before vaccinating Israeli citizens.

[42] 'In the interim, WHO recommends not to use BNT162b2 in pregnancy, unless the benefit of vaccinating a pregnant woman outweighs the potential vaccine risks, such as in health workers at high risk of exposure and pregnant women with comorbidities placing them in a high-risk group for severe COVID-19. Information and, if possible, counselling on the lack of safety and efficacy data for pregnant women should be provided.' WHO, 'Interim recommendations for use of the Pfizer–BioNTech COVID-19 vaccine, BNT162b2, under emergency use listing: interim guidance' (8 January 2021), https://apps.who.int/iris/bitstream/handle/10665/338484/WHO-2019-nCoV-vaccines-SAGE_recommendation-BNT162b2-2021.1-eng.pdf?sequence=1&isAllowed=y (accessed 24 April 2023).

[43] 'There are currently no efficacy or safety data for children or adolescents below the age of 16 years. Until such data are available, individuals below 16 years of age should not be vaccinated'; ibid.

[44] Joffre, note 41.

[45] 'The medical trials at Nuremberg in 1947 deeply impressed *upon the world* that experimentation with unknowing human subjects is morally and legally unacceptable.' *Abdullahi v Pfizer*, 562 F.3d 163, 179 (2d Cir. 2009), citing *United States* v *Stanley*, 483 US 669, 687, 107 SCt 3054, 97 L.Ed.2d 550 (1987).

[46] Ibid.

[47] 'In particular, no one shall be subjected without his free consent to medical or scientific experimentation.' International Covenant on Civil and Political Rights, art 7.

[48] Ibid. Moreover, informed consent is widely understood as constituting a *jus cogens* norm. See, e.g., *Abdullahi v Pfizer*, note 45.

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However, whether or not the mass vaccination program fulfilled the technical strictures of an experiment, informed consent is also mandated when medical treatment is offered. The International Covenant on Economic, Social and Cultural Rights (ICESCR) states that informed consent encompasses medical treatment as well as experimentation.[49] Moreover, in 2005, the General Conference of the United Nations Educational, Scientific and Cultural Organization (UNESCO) adopted the Universal Declaration on Bioethics and Human Rights, mandating 'the prior, free, express and informed consent of the person concerned' for research-oriented treatments which at a minimum the Pfizer-Israel program encompassed.[50] Medical ethics also obligates health care providers to obtain informed consent for treatment.[51]

While further scientific research to advance medical treatment is important, science must yield to human rights which supersedes medical progress: '[M]edical progress is based on research which ultimately must rest in part on experimentation involving human subjects, and that in medical research on human subjects, considerations related to the well-being of the human subject should take precedence over the interests of science and society'.[52]

In a further exemplar of informed consent's crucial importance, the Universal Declaration on Human Genome and Human Rights states regarding treatment or diagnosis, 'In all cases, the prior, free and informed consent of the person concerned shall be obtained.'[53] Even within the context of global coordination to contain epidemics and global health crises, informed consent is required before providing medical treatment. As enumerated in the WHO International Health Regulations (IHR), a health crisis does not outweigh the obligation to obtain informed consent even for ordinary vaccinations. The IHR states:

> No medical examination, vaccination, prophylaxis or health measure under these Regulations shall be carried out on travellers without their prior express informed consent or that of their parents or guardians.
> Travellers to be vaccinated or offered prophylaxis pursuant to these Regulations, or their parents or guardians, shall be informed of any risk associated with vaccination.[54]

In addition, informed consent is mandatory pursuant to Israeli domestic law:

> No medical care shall be given unless and until the patient has given his informed consent to it ... In order to obtain informed consent, the clinician shall supply the

[49] 'The right to health contains both freedoms and entitlements. Freedoms include the right to control one's health, including the right to be free from non-consensual medical treatment and experimentation.' ICESCR, art 12.

[50] UNESCO, 'Universal Declaration on Bioethics and Human Rights', 33 C/Resolution 36 (19 October 2005) art 6.

[51] Timothy Cardozo and Ronald Veazey, 'Informed Consent Disclosure to Vaccine Trial Subjects of Risk of COVID-19 Vaccines Worsening Clinical Disease' (2021) 75 *International Journal of Clinical Practice* e13795.

[52] 'In any research on human beings, each potential subject must be adequately informed of the aims, methods, anticipated benefits and potential hazards of the study and the discomfort it may entail.' Declaration of Helsinki (2000), http://www.wma.net/e/policy/b3/.htm (accessed 24 April 2023) § B.22.

[53] Universal Declaration on Human Genome and Human Rights, https://www.ohchr.org/en/professionalinterest/pages/humangenomeandhumanrights.aspx (accessed 24 April 2023) art 5. See also Article 6 of the Universal Declaration on Bioethics and Human Rights 2005: 'Any preventive, diagnostic and therapeutic medical intervention is only to be carried out with the prior, free and informed consent of the person concerned, based on adequate information. The consent should, where appropriate, be express and may be withdrawn by the person concerned at any time and for any reason without disadvantage or prejudice'.

[54] World Health Organization (WHO), 'International Health Regulations (2005) Part V – Public Health Measures Chapter I – General Provisions', https://www.who.int/publications/i/item/9789241580410 (accessed 24 April 2023), art 23(3)/(4).

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> patient medical information to a reasonable extent, such as to enable the patient to decide whether to agree to the treatment proposed.[55]

Thus, notwithstanding a global health emergency such as the COVID-19 pandemic, informed consent remains an ironclad international legal duty imposed on states.[56] State obligations as exemplified in the ICPPR – including obtaining informed consent – must not be violated.[57] Notwithstanding the obligation to obtain informed consent, as discussed in the next section, the Israeli government did not bother to obtain informed consent.

Israeli Government's Failure to Obtain Informed Consent

As discussed in the subsection above, informed consent is enshrined in international law and clearly constituted an imperative in the context of the Pfizer-Israel Contract. As a *jus cogens* norm emanating from the horrors of World War II, the Israeli government was forbidden to ignore informed consent.[58]

Although it is manifestly clear that the Israeli government was obligated to obtain informed consent before vaccinating Israeli citizens, Israeli vaccine-takers were not asked for their informed consent despite the fact the Pfizer-Israel Contract was essentially 'a "Phase 4" study'.[59] As noted by Professor Gurwitz, the vaccination program lacked transparency, alternatives were not offered, and no consent forms were provided:

> The timely COVID-19 vaccine supply in Israel, unparalleled by other countries, was possible thanks to an agreement between its government and Pfizer, according to which Israel agreed to serve as a real-world testing ground (sort of a 'Phase 4' study) for the vaccine, in return for sharing with Pfizer aggregated information on COVID-19 vaccination and infection rates. However, at time of writing, details of this agreement remain undisclosed. *This lack of transparency, along with the fact that Israeli citizens eligible and willing to receive COVID-19 vaccination were not offered alternative (non-mRNA based) COVID-19 vaccines, and were not asked to sign an*

[55] Patient's Rights Act 1996, https://hamoked.org/files/2013/155880_eng.pdf (accessed 24 April 2023), chapter 4. See also Dorit Rubinstein Reiss and Nili Karako-Eyal, 'Informed Consent to Vaccination: Theoretical, Legal, and Empirical Insights' (2019) 45 *American Journal of Law and Medicine* 357, 383 ('The right to autonomy and the doctrine of informed consent are well established in Israeli law. It is anchored in Israeli law through court rulings which have acknowledged it since the 1990s, the Patient's Rights Act, and legislation which applies to specific treatments').

[56] WHO, note 54, art 57(1).

[57] 'If member states are failing to conduct any analysis of their obligations under the ICCPR in implementing their emergency measures in response to COVID-19, both individuals and the international legal system will suffer.' Richardson and Devine, note 13, 123. While derogation is permitted under emergencies (see Article 4 of the ICCPR), such derogations are limited and must not violate other state obligations.

[58] *Jus cogens* norms are a select group of principles 'accepted and recognized by the international community of states as a whole as a norm from which no derogation is permitted and which can be modified only by a subsequent norm of general international law having the same character', Vienna Convention on the Law of Treaties, https://legal.un.org/ilc/texts/instruments/english/conventions/1_1_1969.pdf (accessed 24 April 2023), art 53. Informed consent is part of the 'elite' subset of norms recognized as *jus cogens*. See Telford Taylor, *Final Report to the Secretary of the Army on the Nuremberg War Crimes Trials under Control Council Law No. 10* (Washington DC: US Government Printing Office, 1949), 107 ('Nuernberg was based on enduring [legal] principles and not on temporary political expedients, and this fundamental point is apparent from the reaffirmation of the Nuernberg principles in Control Council Law No. 10, and their application and refinement in the 12 judgments rendered under that law during the 3-year period, 1947 to 1949').

[59] Gurwitz, note 29.

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> *informed consent to be vaccinated*, contributed to public mistrust in the Israeli vaccination drive.[60]

Full disclosure and transparency are crucial in determining whether one should receive a particular medical treatment. Moreover, an absence of pressure or coercion is essential to make an informed decision.

According to the Nuremberg Code:

> The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision.[61]

A scenario in which risks are downplayed (or not mentioned) while only strongly positive comments are shared, fails to comport with informed consent. The omission of crucial information in the Israeli government's marketing campaign created the perception that the Pfizer mRNA vaccine was fully 'FDA approved and completely safe'. The advertisement featuring the Prime Minister referring to anyone questioning mRNA as 'clowns' because the Pfizer vaccine was 'approved by the Americans' is an exemplar of incomplete or misleading information. Furthermore, while the WHO had in January 2021 stated that the mRNA vaccine was not recommended for pregnant women or children, the Israeli government simply ignored this advice. The Israeli government enthusiastically promoted vaccinations for pregnant women and children notwithstanding the advice of the WHO. Pushing novel mRNA vaccines on pregnant women and children during the time the WHO explicitly opined the contrary and failing to disclose WHO's contrary opinion fails to comport with informed consent. Moreover, in contrast to other states, the Israeli government never provided a consent form. Thus, even assuming *arguendo* a consent form was provided and signed, the Israeli government's intensive marketing campaign which failed to cite potential risks, disclose that the vaccine remained in trial, or provide the FDA Fact Sheet, prevented any ostensible consent from being truly informed.

This article does not suggest that the Pfizer mRNA vaccine is not beneficial or that it should not have been used. Moreover, the Israeli government is certainly entitled to encourage citizens – even strongly – to receive the vaccination. However, the crucial question in determining whether informed consent was obtained is whether or not risks or potential adverse effects were communicated and full disclosure provided. By withholding information that people needed to make an informed choice, or by creating a false impression that the vaccine had been fully approved and was absolutely safe for everyone, there was a lack of informed consent. At a minimum, by failing to inform citizens

[60] Ibid (emphasis added). In stark contrast to the Israeli government's failure to obtain informed consent, other governments did in fact prepare a consent form, although given the magnitude of the unknown risks, some have argued these informed consent forms may have been inadequate to satisfy informed consent obligations. Deirdre T Little et al, 'COVID-19 Vaccination: Guidance for Ethical, Informed Consent in a National Context' (2021) 36 *Issues Law and Medicine* 127 ('The Australian Government has produced a consent form for COVID-19 vaccination and providers of medical indemnity have produced information on how to obtain informed consent for such vaccines. We are concerned these documents are inadequate for informed consent due to missing or unclear information').

[61] 'Nuremberg Code', https://avalon.law.yale.edu/imt/nurecode.asp (accessed 24 April 2023).

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that the Pfizer mRNA vaccine remained in trial, and alternatives existed, the possibility of making an informed decision was eviscerated.[62]

Interestingly, since the roll-out of COVID-19 vaccines, there have been acknowledgements of adverse effects and risks. The most recent FDA Fact Sheet discloses a low, but elevated risk for cardiac problems particularly in young males taking the Pfizer mRNA vaccine.[63] Indeed, the extent and degree of adverse effects is unknowable and are being currently researched.[64] Surely, many recipients within any 'at risk' demographic groups might have selected not to take the risk of cardiac damage had they been informed that risks were unknown rather than being told it was safe and 'had been approved by the Americans'.

Significantly, some governments have decided against vaccinating certain groups as the risks have been deemed by scientists to outweigh the benefits.[65] Indeed, notwithstanding the Israeli government's marketing campaign which created an impression the Pfizer vaccine was 'absolutely safe', short-term and long-term risks were unknown (and indeed unknowable) as it takes years to definitively determine the existence and extent of health risks.[66] The discovery of adverse effects is not surprising given the lack of comprehensive testing. 'The fast-tracking of anti-COVID-19 disease vaccine development has resulted in products with more known unknowns, and unknown unknowns, than any other vaccine in common usage … These unknowns, together with a lack of knowledge of long-term consequences of COVID-19 infection, make the consent process more complex.'[67]

The recipients of the Israeli vaccination program were certainly entitled to the right of informed consent but citizens were not even provided a consent form.[68] The Israeli government failed to abide by international law and deprived citizens of their human right to informed consent.

[62] Moreover, the failure to obtain informed consent might help fuel false narratives, conspiracy theories and reduce the public trust in medical treatment. See Gurwitz, note 29, 3786 ('Assuring that vaccines are administered with informed consent would also be helpful for increasing public trust'). The failure to be transparent and obtain informed consent might endanger future use of important medical treatments as trust in science is eroded.

[63] 'Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have occurred in some people who have received the Pfizer-BioNTech COVID-19 Vaccine, Bivalent, the Pfizer-BioNTech COVID-19 Vaccine, or COMIRNATY (COVID-19 Vaccine, mRNA), more commonly in adolescent males and adult males under 40 years of age than among females and older males'; 'Fact Sheet for Recipients and Caregivers about Pfizer-Biontech Covid-19 Vaccine, Bivalent which has Emergency Use Authorization (EUA) to Prevent Coronavirus Disease 2019 (COVID-19)', https://www.fda.gov/media/167212/download (accessed 24 April 2023).

[64] Berkeley Lovelace Jr, 'Myocarditis after Covid Vaccination: Research on Possible Long-Term Risks Underway' (12 November 2022), https://www.nbcnews.com/health/health-news/myocarditis-covid-vaccine-research-long-term-effects-rcna55666 (accessed 24 April 2023) (reports of heart issues after taking the Pfizer and Moderna vaccines and the long-term studies to determine the extent of damage).

[65] See Robert Hart, 'Germany, France Restricts Moderna's Covid Vaccine For Under-30s Over Rare Heart Risk – Despite Surging Cases' (21 April 2022), https://www.forbes.com/sites/roberthart/2021/11/10/germany-france-restrict-modernas-covid-vaccine-for-under-30s-over-rare-heart-risk-despite-surging-cases/?sh=4d263e3e2a8a (accessed 24 April 2023) (noting a higher risk in young adults being vaccinated including the Pfizer mRNA vaccination although the risk was slightly lower in the Pfizer vaccine).

[66] 'To support FDA approval, most vaccine clinical trials include substantially longer follow-up of trial participants to track both safety and efficacy. For example, for shingles vaccines, participants in Shingrix clinical trials were followed for a median of 3.1 years in one study and 3.9 years in another, and participants in Zostavax clinical trials were followed for a median of 1.3 years in one study and 3.1 years in another.' Philip R Krause and Marion F Gruber, 'Emergency Use Authorization of Covid Vaccines-Safety and Efficacy Follow-up Considerations' (2020) 383 *New England Journal of Medicine* e107.

[67] Little et al, note 60, 129–130.

[68] Gurwitz, note 29.

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Does Pfizer have responsibility for this failure? As discussed below, corporations such as Pfizer are uniquely positioned to utilize leverage to safeguard human rights.

IV. Leveraging Corporate Due Diligence on State Partners

This section discusses corporations utilizing leverage to promote human rights. State regulation of corporations – including using state leverage with businesses – is crucial and should be strengthened. Yet, as explained below, an under-explored potential avenue to defend human rights is for corporations to capitalize on their leverage with states. An enhanced focus on corporations capitalizing on economic leverage is sensible as shifting balances of political-economic power with states has resulted in large corporate actors wielding immense power in the political economy.[69] In particular, multi-national corporations constitute major actors on the global stage and wield enormous influence over national economies and governments.[70]

Safeguarding Human Rights via State Monitoring of the Corporation

The importance of safeguarding human rights is exemplified in the 1948 Universal Declaration of Human Rights where human rights are enshrined as 'a common standard of achievement for all peoples and all nations'.[71] Human rights obligations have been further embedded in various agreements and treaties underscoring the significance of promoting human rights.[72] Conceptually, human rights responsibility has centred on states as they were understood as the sole subjects of international law. <1>However, the conceptualization that only states are the subjects of international law is progressively becoming as state-business distinctions are increasingly blurred.[73] In addition, large global corporations are economically powerful and influential actors. As safeguarding human rights is inextricably linked with economics, international politics and global governance, large global corporations are influential in these spheres of power. Thus, states no longer constitute the exclusive authoritative controllers of political, economic and social life. Large corporations wield substantial influence over governments and a growing consensus has emerged that corporations bear responsibilities to at least not violate or enable violations of international human rights law.[74]

The global trend to impose responsibilities on corporations with respect to human rights gained strength in the 1990s.[75] By 2011, the landmark UNGPs, referred to as the

[69] Catá Backer, note 9, 18; Joel Slawotsky, 'The Global Corporation as International Law Actor' (2012) 52 *Virginia Journal of International Law Digest* 84.

[70] Deva, 'Treaty tantrums', note 3.

[71] See Universal Declaration of Human Rights 1948, Preamble, https://www.un.org/en/about-us/universal-declaration-of-human-rights (accessed 24 April 2023).

[72] See, for example, International Covenant on Civil and Political Rights (1966) and International Covenant on Economic, Social and Cultural Rights (1966).

[73] Jan Wouters and Leen Chanet, 'Corporate Human Rights Responsibility: A European Perspective' (2008) 6 *Northwestern University Journal of International Human Rights* 262 ('Corporations, especially multinational enterprises … have become ever larger and more powerful since the 1970s, often surpassing the economic power and influence of states').

[74] Beth Stephens, 'The Amorality of Profit: Transnational Corporations and Human Rights' (2002) 20 *Berkeley Journal of International Law* 48 (2002) (human rights norms apply to corporations and not only to states).

[75] See, for example, UN Sub-Commission on the Promotion and Protection of Human Rights, Norms on the Responsibilities of Transnational Corporations and Other Business Enterprises with Regard to Human Rights, UN Doc E/CN.4/Sub.2/2003/12/Rev.2 (2003). See also Carolin F Hillemanns, 'UN Norms on the Responsibilities of Transnational Corporations and Other Business Enterprises with Regard to Human Rights' (2003) 4 *German Law Journal* 1065.

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'global standard',[76] provided a crucial framework and mainstreamed the obligations of governments and responsibilities of private corporate actors to act as responsible global citizens.

According to the UNGPs, States should 'protect' and businesses should 'respect' human rights.[77] Not surprisingly, given the classic understanding of state-corporate business relationships, 'protecting' human rights is framed as a state-centric obligation to monitor businesses. Principle 5 of the UNGPs provides: 'States should exercise adequate oversight in order to meet their international human rights obligations when they contract with, or legislate for, business enterprises to provide services that may impact upon the enjoyment of human rights'.[78]

Demonstrating the recognition that states need to engage in oversight of businesses operating in their territory is the increasing willingness of states to legislate corporate accountability laws.[79] The increasing consensus endorsing state oversight on corporations to ensure local populations are protected is an important development in protecting human rights. Is there a method that can be used to help facilitate state compliance with human rights obligations? As discussed below, by engaging in vigorous HRDD, heightened negotiations and inserting human rights compliance language into commercial agreements, corporations can leverage their economic power to promote state compliance with human rights obligations.

Safeguarding Human Rights via Corporate Due Diligence in State Procurement

To analyse the corporate responsibility to perform due diligence, the UNGPs are instructive.[80] In the context of a procurement contract, the responsibility of a state to engage in oversight of corporations is well accepted. Under the UNGPs, states should exercise adequate oversight over businesses when commercial relationships 'may impact upon the enjoyment of human rights'.[81] But the reverse is also equally true. Businesses can use contracts to ensure state compliance when a relationship such as 'the Project' may impact upon the enjoyment of a human right such as informed consent.

While monitoring business partners is often understood in the contexts of parent-subsidiary and/or supply chain partners, such partners can also include states.[82] Indeed, the UNGPs envision partners as encompassing a 'State entity directly linked to its business operations'.[83] While this conceptualization is between a business and a state-linked business

[76] 'The responsibility of business enterprises to respect human rights, as formulated in the [United Nations Guiding Principles on Business and Human Rights, or UNGPs], is a global standard of expected conduct for all business enterprises wherever they operate', *Friends of the Earth Netherlands (Milieudefensie) v Royal Dutch Shell*, District Court The Hague, Judgment of 26 May 2021, English translation at http://deeplink.rechtspraak.nl/uitspraak?id=ECLI:NL:RBDHA:2021:5339, para 4.4.13.

[77] UNGPs, note 4, Pillars I and II. It is worth noting that some believe that businesses lack obligations under international law and point to the fact the UNGPs have adopted the term 'impacts' rather than 'abuses' or 'breaches'.

[78] UNGPs, note 4, Principle 5.

[79] See notes 1–7 and the accompanying text.

[80] David Birchall, 'Any Act, Any Harm, to Anyone: The Transformative Potential of "Human Rights Impacts" under the UN Guiding Principles on Business and Human Rights' (2019) *Oxford Human Rights Hub Journal* 120.

[81] UNGPs, note 4, Principle 5.

[82] 'For the purpose of these Guiding Principles a business enterprise's "activities" are understood to include both actions and omissions; and its "business relationships" are understood to include relationships with business partners, entities in its value chain, and any other non-State or State entity directly linked to its business operations, products or services', UNGPs, note 4, Commentary to Principle 13.

[83] Ibid, Principle 13.

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entity, there is no reason to narrowly restrict the understanding of a partner to a state-linked or state-owned enterprise as opposed to the state itself.[84]

This perspective yields substantial promise: a corporation can use its commercial leverage to incentivize states to comply with human rights obligations. Particularly in the context of procurement contracts, engaging in HRDD and utilizing leverage carries great potential.[85] Doing so also comports with the recognition that ignoring state conduct arising from the performance of the contract which conflicts with human rights compliance is inadequate to fulfil the corporate responsibility to respect human rights. Businesses must be proactive in fulfilling their responsibility to respect human rights, rather than ignoring whether or not a state business partner respects human rights. Businesses have a responsibility to respect human rights independent of state conduct:

> The responsibility of business enterprises to respect human rights.... exists independently of States' abilities and/or willingness to fulfil their own human rights obligations and does not diminish those obligations. And it exists over and above compliance with national laws and regulations protecting human rights. *Therefore, it is not enough for companies to monitor developments and follow the measures States take; they have an individual responsibility.*[86]

Corroborating the logic of this approach, the UNGPs conceptualize the corporate responsibility to respect human rights holistically to encompass human rights violations arising from the business relationship even if the corporation might not have engaged directly in the misconduct. Businesses must:

> (a) Avoid causing or contributing to adverse human rights impacts through their own activities, and address such impacts when they occur, (b) Seek to prevent or mitigate adverse *human rights impacts that are directly linked to their operations, products or services by their business relationships, even if they have not contributed to those impacts.*[87]

In the context of government procurement contracts, and particularly with respect to collaborations with states to tackle global challenges such as a pandemic, corporations have a unique opportunity to prevent human rights abuses committed by state partners. For example, in the Pfizer-Israel collaboration, it was insufficient for Pfizer to rely on the Israeli government to satisfy Pfizer's responsibility to respect. I explore below what Pfizer could have done to fulfil its responsibility to respect human rights.

[84] States can also be partners and collaborators with corporations as exemplified in the Pfizer-Israel data-sharing agreement.

[85] Catá Backer, note 9, 28–29 ('Rule and technique merge in a context in which international norms are adopted as binding within the governance universe of corporate operations; soft law becomes hard within the internal governance frameworks of the enterprise and, thus internalized, the techniques of corporate management – contract, standards, internal policy, monitoring, and discipline – become central to the construction of rule systems derived from their constituting normative basis in international "soft law".').

[86] *Milieudefensie*, note 76, paras 4.4.13–4.4.14.

[87] UNGPs, note 4, Principle 13 (emphasis added). Ryngaert notes: 'from a liability perspective, involvement of corporations in overseas human rights abuses often results from *negligent behaviour* rather than direct perpetration: the corporation failed to prevent human rights abuses committed by other – foreign-based – actors over whom it exercised a measure of control, such as subsidiaries, branches, offices, contractors, and suppliers'. Cedric Ryngaert, 'Accountability For Corporate Human Rights Abuses' (2018) 29 *Criminal Law Forum* 1, 4 (emphasis in original).

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What Should Corporations Do? The Exemplar of the Pfizer-Israel Contract

Leverage is a powerful tool that can be used by states in procurement to promote business compliance with human rights.[88] But leverage is a two-way street: in various contexts, businesses can also use leverage to promote state compliance with human rights. Pursuant to Principle 19 of the UNGPs, a business should conduct due diligence and take appropriate measures based on these findings:

> Appropriate action will vary according to: (i) Whether the business enterprise causes or contributes to an adverse impact, or whether it is involved solely because the impact is directly linked to its operations, products or services by a business relationship; (ii) The extent of its leverage in addressing the adverse impact.[89]

Pfizer should have performed due diligence to ascertain the existence of any human rights impacts arising from the Pfizer-Israel Contract. Leverage is key and the Commentary to Principle 19 emphasizes how business can marshal their economic strength to incentivize the protection of human rights by its partners.[90] Pfizer's enormous leverage with the Israeli government was extensive. Pfizer was the first manufacturer to receive an EUA and CEO Bourla described the Israeli Prime Minister's incessant calling which provided great leverage for Pfizer to insist on informed consent being part of the contract. Pfizer had the opportunity, from the earliest stage of negotiation, to discuss informed consent. In addition, during all of these discussions, Pfizer could have offered to provide advice regarding informed consent to build the Israeli government's capacity to comply with their duty to obtain informed consent. By engaging directly with the Israeli Prime Minister, Pfizer could have 'short-listed' the issue of informed consent. Pfizer could have used their leverage at each stage of the public procurement process, from the Netanyahu-Bourla consultations, contract negotiations, and execution to insert informed consent into the Contract.

As a first step, Pfizer should have conducted HRDD 'as early as possible in the development of a new activity or relationship, given that human rights risks can be increased or mitigated already at the stage of structuring contracts or other agreements'.[91] This initial responsibility to perform due diligence and evaluate potential human rights risks is crucial.[92] Ideally, Pfizer would have identified the Israeli government's duty to obtain informed consent from Israeli citizens prior to vaccination. Admittedly, it is unknown whether Pfizer endeavoured to perform HRDD with respect to identifying human rights risks such as the right to informed consent. However, nowhere in the heavily redacted Pfizer-Israel Contract does Pfizer insist on (let alone mention) an obligation to obtain informed consent.[93] This omission stands in stark contrast to other legal obligations that Pfizer specifically enumerated in the Contract such as compliance

[88] 'Public buyers, as large scale consumers of goods, hold significant leverage over the behaviour of brands and retailers in global supply chains … states tend to use their discretion to promote domestic social issues through public procurement', Martin-Ortega, note 1, 75.

[89] UNGPs, note 4, Principle 19.

[90] Ibid, Commentary to Principle 19.

[91] UNGPs, note 4, Principle 17.

[92] This preliminary obligation to conduct HRDD in relation to business partners has been incorporated in several laws. See, e.g., the French Duty of Vigilance Law.

[93] There is a very small possibility that informed consent is mentioned in the redacted portions. However, this possibility would appear quite remote and it would not make any sense to hide such a legal obligation particularly when Pfizer placed other legal duties in the Contract which were not redacted. The article therefore proceeds with the presumption that the term 'informed consent' does not appear within the redacted portions of the Contract.

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with the Foreign Corrupt Practices Act[94] as well as various other 'Regulatory Requirements' such as 'Privacy Protection … Pharmacist regulations … [and] Global Trade Control Laws'.[95]

Pfizer's failure to insert a clause on informed consent into the Pfizer-Israel Contract was a failure to capitalize on its enormous leverage to raise a vital human rights concern at the commencement of contract negotiations. As a large pharmaceutical entity with a product in great demand, Pfizer should have capitalized on its enormous leverage and insisted that the Israeli government comply with informed consent from the outset. Moreover, as this was a data-sharing collaboration, it would have been relatively easy for Pfizer to insert into the contract some clause to the effect that along with the data to be transferred to Pfizer such as age, sex, and other criteria, an additional data point could have been added, i.e., confirmation that informed consent was obtained.

Moreover, while absolutely a vital first step, merely performing the initial assessment is insufficient. Pfizer had a continuous responsibility to perform HRDD and to assess potential human rights risks associated with the procurement contract. Ongoing monitoring is critical as noted in the UNGPs: 'Because human rights situations are dynamic, assessments of human rights impacts should be undertaken at regular intervals: prior to a new activity or relationship; … *and periodically throughout the life of an activity or relationship*'.[96]

Pfizer could have also reached out and consulted with Israeli human rights organizations to ascertain whether informed consent was being obtained, constituting an integral aspect of oversight of its partner. Moreover, Pfizer could have utilized its leverage in various additional ways to fulfil its responsibility to respect human rights. For example, Pfizer could have offered its experience as a large pharmaceutical business which has conducted numerous clinical trials and provided advice to the Israeli government on informed consent. Pfizer could also have worked with the Israeli government to develop an informed consent form. Yet, Pfizer either did not perform HRDD or had no interest in ensuring that the human right to informed consent was respected by the Israeli government.

There are lessons to be learned from the Pfizer-Israel experience with respect to the corporate responsibility to respect human rights applicable to future global pandemics or other emergencies.[97] Once Pfizer decided to engage in a business relationship with the Israeli government, Pfizer should have performed due diligence to identify potential human rights issues arising from the Pfizer-Israel business relationship such as the Israeli government's duty to obtain informed consent.[98] In addition, Pfizer should have discussed and negotiated contractual language addressing informed consent, and established an oversight mechanism to ensure compliance so violations would be flagged

[94] 'Epidemiological Evidence Collaboration Agreement', note 16.

[95] Ibid, section 1.9.

[96] UNGPs, note 4, Commentary to Principle 18 (emphasis added).

[97] 'If international law does not implement efficient therapies, human rights – including freedom of movement – will continue to fall victim to future pandemic outbreaks', Fernando Dias Simões, 'Protecting International Travelers During Pandemics: Charting the Way Forward' (2022) 31 *Minnesota Journal of International Law* 41, 54.

[98] 'Human rights due diligence laws require not only serious engagement by companies, but the continued involvement of trade unions, civil society and other stakeholders. They also demand an active role as well as sufficient competences and resources in the agencies charged with their enforcement. The two laws represent important contributions to the state duty to protect and the corporate responsibility to respect human rights. Guarantees for access to remedy are limited in both laws, however, and this is arguably where mandatory measures currently are most needed', Markus Krajewski, Kristel Tonstad and Franziska Wohltmann, 'Mandatory Human Rights Due Diligence in Germany and Norway: Stepping, or Striding, in the Right Direction? (2021) 6:3 *Business Human Rights Journal* 550, 558.

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and subsequently remedied. Particularly during times of crisis, the safeguarding of human rights must be sacredly defended.[99] Utilizing contracts is a potentially important mechanism to promote the safeguarding of human rights.[100]

V. Conclusion

This article utilized the case study of the Pfizer-Israel Contract to examine the corporate responsibility to respect human rights. As the manufacturer who received the first EUA, and as demonstrated by the Israeli Prime Minister's persistence in contacting Pfizer's CEO, Pfizer had substantial leverage with the Israeli government. Pursuant to the UNGPs, Pfizer's HRDD should have raised informed consent as a potential human rights risk arising from the contract's performance. Utilizing Pfizer's leverage which existed from the initial consultations, through negotiations and ultimate contract execution, Pfizer should have inserted language into the contract regarding the Israeli government's duty to obtain informed consent.

Yet, despite ample opportunity, there is no reference to informed consent in the redacted contract. Whether Pfizer even performed HRDD is questionable but even assuming *arguendo* Pfizer performed it, nothing in the contract references any obligation on the Israeli government to obtain informed consent. Pfizer could have embedded into the Contract a mechanism to ensure timely reporting to Pfizer with respect to the Israeli government's compliance with informed consent. This is particularly noteworthy because Pfizer contractually obligated the Israeli government to provide data – adding a requirement to obtain informed consent could have been part of the data transfer. Moreover, Pfizer failed to implement any effective control mechanism to ensure informed consent was obtained. Furthermore, as a large pharmaceutical business, Pfizer could have shared with the Israeli government its expertise regarding informed consent and worked with the Israeli government to develop an informed consent form. By failing to undertake these measures, Pfizer failed to fulfil its responsibility to respect human rights.

Finally, while the corporate responsibility to respect human rights exists even with routine procurement contracts, in the context of actual collaborations, such as the Pfizer-Israel Contract, this responsibility to respect is even more compelling. A holistic examination of the relationship suggests a more extensive connection than a mere procurement contract. Pfizer's CEO conceded in an NBC interview that Israel serves as Pfizer's global laboratory for the mRNA vaccine, suggesting that the Israeli program constitutes more than an ordinary procurement contract. The Contract's language as well as the remarks of both the Pfizer CEO and the Israeli Prime Minister described a role for the Israeli government substantially exceeding a routine contract. Yet, the Israeli government's obligation to obtain informed consent was seemingly of no import to Pfizer. Pfizer's failure to fulfil its responsibility to perform HRDD (or to ignore any internal findings) as well as the failure to insert contractual language regarding informed consent, is a glaring exemplar of a missed opportunity to use leverage to promote respect for human rights.

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[99] See Richardson and Devine, note 13, 123 ('If member states are failing to conduct any analysis of their obligations under the ICCPR in implementing their emergency measures in response to COVID-19, both individuals and the international legal system will suffer').

[100] See Catá Backer, note 1, 483.

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