

# Health and law-making: collectively re-creating narratives

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## 1. Introduction

Since childhood, we learn that knowledge does not come from ourselves (schoolchildren), but from “an omniscient master”. When a crisis happens – a disease, a change in our environment – we similarly rely on external authorities, who are usually prompt to provide us with directives. But is this the most effective way to take care of our very needs to overcome complex challenges (Oxfam, 2021; V-Dem Institute, 2021; Rushkoff, 2019; Medina, 2013)? Can a few enlightened individuals be more knowledgeable than the multitude (Raymond, 1999; Okolloh 2009; Falkvinge 2013)?

Is the centralization of power during an emergency still legitimate when the Internet allows thousands of people to put in common their resources (e.g., online hackathons (Balli, 2021)), and to decide within hours (e.g., digital democracy (Manicini, 2015; European Parliament, 2020; TA Swiss et al., 2021))?

During this participatory discussion, we will explore the narratives behind “health” and “law” policy-making centralization. We will explore how people can reclaim ownership of themselves, control over their medical journey and medical information (e.g., health commons (Balli 2021a; b)), critical public health (Greenhalgh, 2009)). We will also discuss how individuals and communities can reclaim the right to elaborate rules that affect them and their coordination (legal commons, democratic constitutionalism (Bailey and Mattei, 2013; Vergara, 2020; Boal, 1999; Laugeri, 2020)).

Finally, we will reflect on Elinor Ostrom's (2009) statement that “a core goal of public policy should be to facilitate the development of institutions that bring out the best in humans”. Thus we will introduce the work done in other fields by legal scholars working on indigenous law (Canada, Switzerland) (Banville et al, 2020; Knoepfel and Sheweizer, 2015), and on changing propriety (Italy) with reflections on how this can inspire health commons policy development (Italian Ministry of Justice, 2007; Vercellone, 2020; Italian Court of Cassation, 2011).

We adopted a bottom-up approach to collectively building a Knowledge Commons (KC) for the colloquium. We organized the session for participants to discuss among themselves and report on their conclusions. We built sub-groups of 5-7 people to foster interaction among all participants (Aubé et al, 2011). Then, each sub-group presented its key discussion outcomes. This allowed us to aggregate different perspectives that you will find compiled hereunder in this paper. Our reflections are documented and available online, on a public [MediaWiki](#); it can be enriched autonomously by interested individuals (after [creating an account](#)). The content of this wiki is under a [Creative Commons Attribution ShareAlike 4.0 license](#). Additionally, MediaWiki is free/libre and open-source software (FLOSS) (Free Software Foundation, 2021; Open Source Initiative, 2017), which means interested communities can freely use, reproduce, enhance and adapt the software – another commons. Our intent is to remove barriers to access, production, and dissemination of knowledge around this topic. Our approach is aligned with the UNESCO (2021) recommendation on open science, which encourages discussions and co-creation of open scientific knowledge.

## 2. Recreating the narrative on Health regulation – First perspective: The medical regulation challenge

A private legal entity must comply with medical device regulations (US Food and Drug Administration [FDA], European Medicines Agency [EMA]) and manufacture and commercialize the medical device. Thus, medical device regulatory bodies require quality management systems often incompatible with a volunteer-based organization (Abuhav, 2018). Regulators acknowledge benefits from open-source hardware (OSH) communities; hence they progressively adapted their regulation first to frame the use of smartphones as medical devices (FDA, 2013), then they regulated the increasing use of 3D printing in the medical sector (FDA, 2018). Finally, during the COVID-19 pandemic, they proposed an emergency regime (e.g., building ventilators).

Still regulators' needs are extremely stringent and quite challenging to achieve for a community of volunteers. Conscious of these limitations, some regulators, like the Australian one, made a specific statement regarding Diabetes control systems (2018):

“We recognise that **health professionals cannot recommend DIY [do it yourself] technologies** to people with diabetes. Health professional recommendations should be for devices that have been approved through the regulatory process for safety and effectiveness. However, **there will always be some people who accept a level of risk and choose to take the DIY approach. These people should continue to receive support and care** from their diabetes healthcare professional and the health system.”

Opinion of the attendees and way forward: Our attendees collectively agreed that the Australian approach is an acceptable middle ground where transparency and responsibility allow each individual to make an informed decision regarding their own risk profile and decide whether or not to use a DIY device on itself.

Participants wondered to which extent the creation of standards could help to structure the OSH ecosystem to make the regulation lighter or easier to enforce.

Financing open-source projects: One of the challenges OSH communities face is the financial valuation of the goods their produce. Unlike FLOSS projects, OSH projects are cash intensive, and funds are rapidly needed to scale up a collective innovation. Unfortunately, Venture Capitals or Banks struggle with the estimation of community assets and are very reluctant in the absence of patents protecting these assets to invest in these open projects. Interestingly, when universities push innovations, they tend to be quickly enclosed by private entities if considered relevant.

Opinion of the attendees and way forward: Participants highlighted the role that health insurance could take in financing these cost-effective, innovative projects and globally encouraging open approaches.

Globally, securing fair compensation for volunteers investing time and energy in these open-source solutions has been confirmed as a concern by the group. The protection from free riding, particularly in the OSH field where copyright protection is only partial and patenting too costly, stood out as a legitimate concern. Very often, the absence of a market protects communities from the problem and limits their ability to make a significant impact.

Indeed, the most prominent issue for the future success of OSH communities in the health sector is related to regulatory bodies and the financial system. Regulators and financial system players must acknowledge the post-COVID-19 paradigm shift; an ever-increasing number of innovations can be created above and beyond the OSS world. Thus policymakers need to create the conditions to secure these innovations to allow them to thrive legally.

### 3. Recreating the narrative on Health regulation – Second perspective

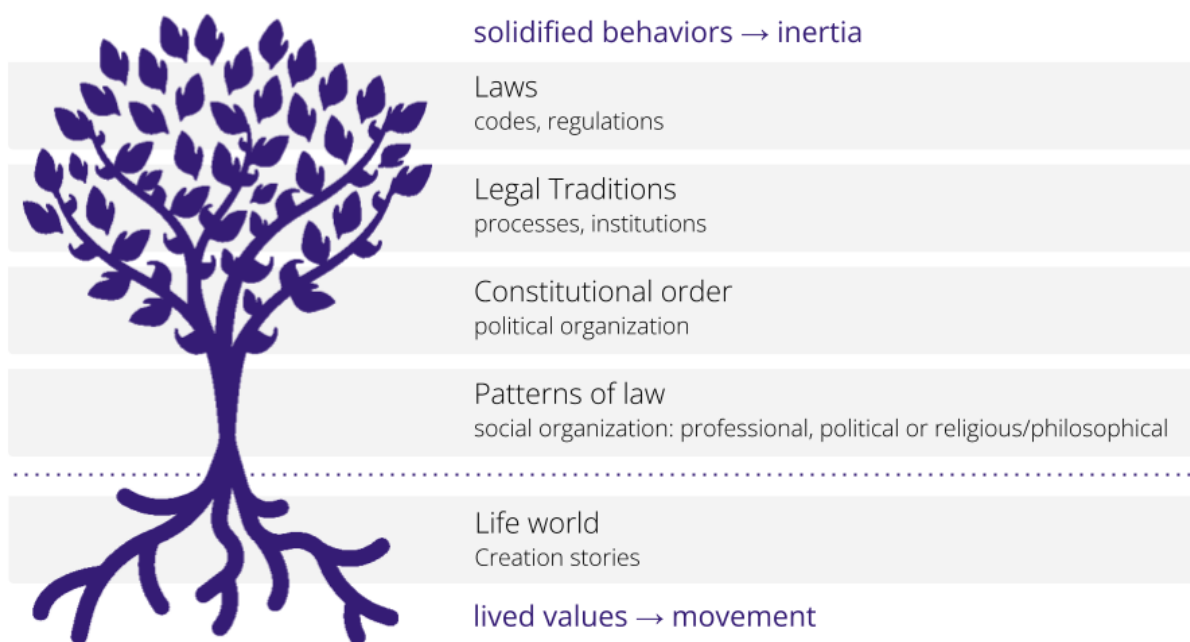
Can we heal without redefining the rules that affect us? The purpose of medical regulations “to identify and monitor significant adverse events involving medical devices. The goals of the regulation are to detect and correct problems in a timely manner.” (FDA, 2020). Hence, another approach to tackle this aim is to align with the spirit of the law, rather than solely complying with the written code. Critical public health and democratic constitutionalism can provide valuable inputs to such questioning.

Critical public health is an approach that invites us to recognize and challenge socio-economic barriers to good health, exploring to which extent certain institutions, regulations, processes or agents may be oppressive or allies (Greenhalgh, 2009).

Here, we can reflect on **whether medical regulations increase or hinder the capacity of a community of peers to rapidly identify and mitigate risks** related to self- and mutual care, respectively the co-creation of shared knowledge and technologies. In fact, many quality management systems are often implemented by decision of a third-party, rather than by a collective agreement among all actors of the ecosystem. Hence, **most actors may not find an intrinsic motivation in implementing such an approach** (Gelinias, 1984). Similarly, medical devices thought by experts without a continuing involvement of end users – including in strategic decision-making – may result in products that either do not fit local realities, or a long-term use (van Dulmen et al, 2007; Compton et al, 2018).

A community co-creating a technology for their peers rather than for profit will possibly cumulate different advantages: personal engagement and passion, the will to put in commons complementarities to build collective wisdom, and a personal concern in mitigating risks so that others may adopt the technology knowing the collective effort made, but also assuming a form of sovereignty in taking their part of responsibility over use of technology. Additionally, OSH peer production can help impoverished communities to access medtech, and adapt these to local contexts, thanks to the rights to use, repair, reproduce, improve, and adapt (He and al, 2021; Al-Faruque, 2022) – consequently reducing the cost of innovation (Moritz et al, 2019). Indeed, it “is a very important need to increase access to medical devices to meet healthcare needs” (World Health Organization, 2016).

Democratic constitutionalism is another approach that invites us to remember “the will of the people as having a higher constitutional value than the will of Parliament” (Bailey and Mattei, 2013). In fact, regulations are of much lesser priority in the hierarchy of law than the constitutional process.



CC BY-SA by F Balli. Inspired by [Capra F, Mattei U. The Ecology of Law](#). Adapted from [Banville MS, Lapalme J. Property Rights / Property Wrongs](#). Icons: Freepik at flaticon.

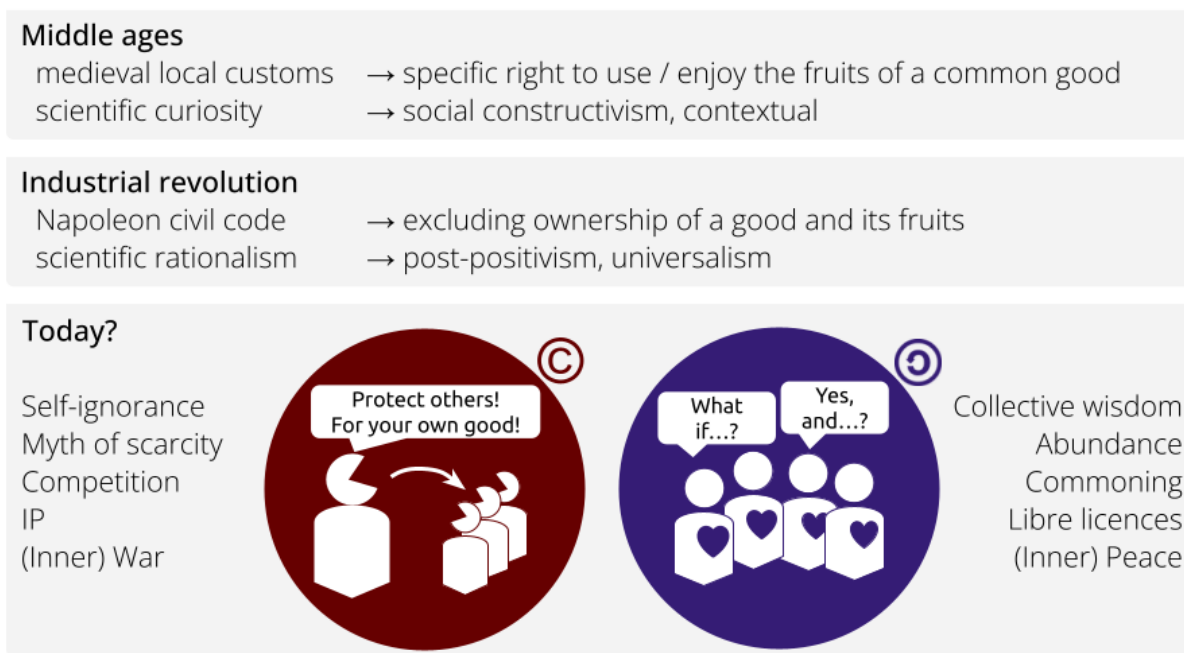
Here, we can reflect on the extent to which medical regulations are aligned with higher collective interests and legal principles. For example, the intensive resources required to obtain medical certifications hinders transdisciplinary communities motivated by the collective wellbeing to enter such processes, while industries may receive a certification even when putting people's lives at risk (Lundh et al, 2012; Dhruva et al, 2009). OSH projects have an essential benefit in comparison to industry's practices: a commitment to ensure gratis online access to the fabrication recipe of the device, and sometimes even to the full iteration process.

As one human out of two cannot afford essential medical care (World Bank and World Health Organization, 2017), looking critically at the socio-economic barriers to health, and reflecting on the sovereignty communities should have in co-creating knowledge and technologies for the commons is vital. Indeed, as Capra and Mattei (2015) suggest, "If the people were to understand the nature of law [and health] as an evolving common, reflecting local conditions and fundamental needs, they would care about it. People would understand that the law [and health are] too important to remain in the hands of organized corporate interests".

In this regard, it may be interesting to draw parallels with the paradigm shift requested by the Italian Court of Cassation following the work done by the Rodotà Commission (Italian Ministry of Justice, 2007):

Where an immovable property, regardless of the owner, is, due to its intrinsic connotations [...] intended for the realization of the welfare state [...], this property is to be considered, beyond the now outdated perspective of Roman dominium and code-related ownership, "commons", that is, regardless of the title of ownership, instrumentally linked to the realization of the interests of all citizens (Italian Court of Cassation, 2011, translated by Vercellone, 2020, p. 8).

Could we then envision an ecosystem where regulations would emerge from communities federated around the co-creation of freely reproducible knowledge and technologies?



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As the industrial revolution brought excluding ownership, universalism and technology solutions, it may be of interest to explore "Ancient Intelligence," notably , shared rights of use, non-written laws such as indigenous local customs, and solidarity-driven solutions (Banville et al, 2020; Knoepfel and Schweizer, 2015)?

#### **4. Discussion and way forward**

A consensus emerged amongst colloquium participants; a balance between top-down regulation and bottom-up agility and autonomy has to be found to individualize healthcare treatments and devices.

The central point in this debate was transparency on health-related matters. Without transparency on personal data produced and controlled within proprietary medical technologies, providing meaningful informed consent to personal data collection and management is highly challenging. Ultimately, the absence of openness prevents individuals from adequately assessing medical-related risks and making appropriate decisions.

The same way that Stallman transformed copyright laws into copyleft with an intellectual jujitsu and guaranteed individuals the liberty to use, study, modify and distribute a product of the mind (Betz and Edwards, 1996). This has to be translated in the hardware field to combine top-down and bottom-up paradigms.

## References

Workshop material is accessible online at: [IASC Health and Law, Whiteboard](#) and on the WikiMedia page : [https://houseofcommons.ch/wiki/index.php?title=Health\\_and\\_law-making:\\_collectively\\_re-creating\\_narratives](https://houseofcommons.ch/wiki/index.php?title=Health_and_law-making:_collectively_re-creating_narratives)

- Abuhav I. (2018). *ISO 13485: 2016: A Complete Guide to Quality Management in the Medical Device Industry*. CRC Press.  
<https://www.routledge.com/ISO-134852016-A-Complete-Guide-to-Quality-Management-in-the-Medical-Device/Abuhav/p/book/9781138039179>
- Al-Faruque F. (2022). Medtech remanufacturing is the new battleground for right-to-repair advocates. *Regulatory News*.  
<https://www.raps.org/news-and-articles/news-articles/2022/4/medtech-remanufacturing-is-the-new-battleground-fo>
- Bailey S, Mattei U. (2013). Social Movements as Constituent Power: The Italian Struggle for the Commons. *Indiana Journal of Global Legal Studies* 20(2).  
<https://www.repository.law.indiana.edu/ijgls/vol20/iss2/14>
- Balli F, Ibbotson R, Chhabra V, Pimentel JP, Suturin V, Falcon L, Timm-Bottos J, Kellner E, Menon J, Matringe M, le Couedic C. (2021a). Open-source respiratory health commons. 15 projects communities can adapt, repair, reproduce for low cost medical care (libre and open-source tech). General meeting of the Global Alliance against chronic Respiratory Diseases 2020-2021. *Zenodo*.  
<https://doi.org/10.5281/zenodo.5515632>
- Balli F, Matringe M, le Couedic C, Schull J, Gautam S, Jandard P, Kellner E, Anastasaki A, Serada K, Brahmachari SK, Winter L, Lonchamp P, Schoeller F, Krishnakumar A, Greshake B, Lhoste K, Parot C, Jeanmaire G. (2021b). Health technology as commons: trustable, affordable, adaptable. Geneva Health Forum Open Village. *Zenodo*. <https://doi.org/10.5281/zenodo.4327587>
- Balli F. (2021c). Global crises, democratic solutions—within days. Using Internet to empower citizens, reach popular consensus, and ensure democratic decision-making [Preprint]. *Zenodo*.  
<https://doi.org/10.5281/zenodo.5497574>
- Balli F. (2021d). Team-building and information flow for large groups such as online hackathons - Updated Feb 2021. *Zenodo*. <https://doi.org/10.5281/zenodo.3743244>
- Banville MS, Lapalme J. (2020). Property Rights / Property Wrongs: Micro-Treaties with the Earth. Rethinking our responsibilities towards nature through land stewardship. *Dark Matters Laboratories*.  
<https://provocations.darkmatterlabs.org/property-rights-property-wrongs-micro-treaties-with-the-earth-9b1ca44b4df>
- Betz D, Edwards J. (1996). “Richard Stallman discusses his public-domain [sic] Unix-compatible software system with BYTE editors,” *BYTE* (July,). (Reprinted on the GNU Project web site: <http://www.gnu.org/gnu/byte-interview.html>.)
- Boal A. (1999). *Legislative Theatre. Using performance to make politics*. Routledge.  
<https://www.routledge.com/Legislative-Theatre-Using-Performance-to-Make-Politics/Boal/p/book/9780415182416>
- Capra F, Mattei U. (2015). *The Ecology of Law: Toward a legal system in tune with Nature and Community*. Berrett-Koehler. <https://www.bkconnection.com/books/title/the-ecology-of-law>
- Compton B, Barash DM, Farrington J, Hall C, Herzog D, Meka V, Rafferty E, Taylor K, Varghese A. (2018). Access to medical devices in low-income countries: Addressing sustainability challenges in medical device donations. *National Academy of Medicine Perspectives*.

<https://doi.org/10.31478/201807a>

- Dhruva SS, Bero LA, Redberg RF. (2009). Strength of study evidence examined by the FDA in premarket approval of cardiovascular devices. *JAMA* 302. <https://doi.org/10.1001/jama.2009.1899>
- Diabetes Australia. (2018). Diabetes Australia position statement - DIY technology for type 1 diabetes. <https://static.diabetesaustralia.com.au/s/fileassets/diabetes-australia/ee67e929-5ffc-411f-b286-1ca69e181d1a.pdf>
- European Parliament. (2020). *Digital democracy Is the future of civic engagement online?* [https://www.europarl.europa.eu/RegData/etudes/BRIE/2020/646161/EPRS\\_BRI\(2020\)646161\\_EN.pdf](https://www.europarl.europa.eu/RegData/etudes/BRIE/2020/646161/EPRS_BRI(2020)646161_EN.pdf)
- Falkvinge R. (2013). *Swarmwise. The tactical manual to changing the world.* CreateSpace. <https://falkvinge.net/files/2013/04/Swarmwise-2013-by-Rick-Falkvinge-v1.1-2013Sep01.pdf>
- Gelin A. (1984). Evaluation et multirationalité. Dans C Paquet. Des pratiques évaluatives. NHP. [https://cap.banq.qc.ca/notice?id=p%3A%3Ausmarcdef\\_0000017356&locale=fr](https://cap.banq.qc.ca/notice?id=p%3A%3Ausmarcdef_0000017356&locale=fr)
- Greenhalgh T. (2009). Patient and public involvement in chronic illness: beyond the expert patient. *BMJ* 338. <https://doi.org/10.1136/bmj.b49>
- He S, Lai D, Lee J. (2021). The medical right to repair: the right to save lives. *The Lancet* 397(10281). [https://doi.org/10.1016/S0140-6736\(21\)00445-1](https://doi.org/10.1016/S0140-6736(21)00445-1)
- Italian Court of Cassation. (2011). *Blue Valley Srl vs Ministero delle Infrastrutture e dei Trasporti, Ministero dell'Economia e delle Finanze.* [https://www.labsus.org/wp-content/uploads//images/M\\_images/sentenza3811.doc](https://www.labsus.org/wp-content/uploads//images/M_images/sentenza3811.doc)
- Italian Ministry of Justice. (2007). *Commissione Rodotà - per la modifica delle norme del codice civile in materia di beni pubblici.* [https://www.giustizia.it/giustizia/it/mg\\_1\\_12\\_1.wp?contentId=SPS47617](https://www.giustizia.it/giustizia/it/mg_1_12_1.wp?contentId=SPS47617)
- Knoepfel P, Schweizer R. (2015). Le local et le global : quatre défis de la codification du droit foncier dans le cadre du processus de rédaction du code civil suisse de 1907. In Ponsonnet M, Travési C. *Les conceptions de la propriété foncière à l'épreuve des revendications autochtones : possession, propriété et leurs avatars.* Pacific-Credo. <https://doi.org/10.4000/books.pacific.330>
- Laugeri M. (2020). Emerging Change: a new Transactional Analysis frame for effective dialogue at work. *Transactional Analysis Journal.* <https://doi.org/10.1080/03621537.2020.1726660>
- Lundh A, Sismondo S, Lexchin J, et al. (2012). Industry sponsorship and research outcome. *Cochrane Database Systematic Review* 12. <https://doi.org/10.1002/14651858.MR000033.pub3>
- Mancini P. (2015). Why it is time to redesign our political system. *European View* 14(1). <https://doi.org/10.1007/s12290-015-0343-9>
- Medina J. (2013). *The Epistemology of Resistance – Gender and Racial Oppression, Epistemic Injustice, and the Social Imagination.* Oxford. <https://doi.org/10.1093/acprof:oso/9780199929023.001.0001>
- Moritz M. et al. (2019). On the Economic Value of Open Source Hardware – Case Study of an Open Source Magnetic Resonance Imaging Scanner. *Journal of Open Hardware* 3(1). <https://doi.org/10.5334/joh.14>
- Okolloh O. (2009). *Ushahidi or 'testimony': Web 2.0 tools for crowdsourcing crisis information. Participatory Learning and Action.* <https://pubs.iied.org/g02842>

- Ostrom E. (2009). Beyond markets and states: polycentric governance of complex economic systems. Prize lecture. *The Sveriges Riksbank Prize in Economic Sciences in Memory of Alfred Nobel*. [https://www.nobelprize.org/uploads/2018/06/ostrom\\_lecture.pdf](https://www.nobelprize.org/uploads/2018/06/ostrom_lecture.pdf)
- Oxfam. (2021). *The hunger virus multiplies: deadly recipe of conflict, covid19 and climate accelerate world hunger*. [https://oi-files-d8-prod.s3.eu-west-2.amazonaws.com/s3fs-public/2021-07/The%20Hunger%20Virus%20202.0\\_media%20brief\\_EN.pdf](https://oi-files-d8-prod.s3.eu-west-2.amazonaws.com/s3fs-public/2021-07/The%20Hunger%20Virus%20202.0_media%20brief_EN.pdf)
- Raymond E. (1999). The cathedral and the bazaar. *Knowledge, Technology & Policy* 12. <https://doi.org/10.1007/s12130-999-1026-0>
- Rushkoff D. (2019). *Team Human*. WW Norton. <https://rushkoff.com/books/team-human-book/>
- TA Swiss, vdf Hochschulverlag AG, Bieri U, Braun Binder N, Salerno S, Keller T, Kälin M. (2021). *Where democracy and digitisation meet. Abridgement of the project «Democracy and digitisation»*. <https://doi.org/10.5281/zenodo.5187686>
- US Food and Drug Administration. (2013). *Mobile medical applications guidance for industry and Food and drug administration staff*. <https://www.federalregister.gov/documents/2013/09/25/2013-23293/mobile-medical-applications-guidance-for-industry-and-food-and-drug-administration-staff>
- US Food and Drug Administration. (2018). *Technical considerations for additive manufactured medical devices: guidance for industry and Food and Drug Administration staff*. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/technical-considerations-additive-manufactured-medical-devices>
- US Food and Drug Administration. (2020). *Overview of Device Regulation*. <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/overview-device-regulation>
- V-Dem Institute. (2021). *Autocratization Turns Viral. Democracy Report 2021*. <https://www.v-dem.net/files/25/DR+2021.pdf>
- van Dulmen S, Sluijs E, van Dijk L. et al. (2007). Patient adherence to medical treatment: a review of reviews. *BMC Health Services Research* 7. <https://doi.org/10.1186/1472-6963-7-55>
- Vercellone A. (2020). The italian experience of the commons: right to the city, private property, fundamental rights. *The Cardozo Electronic Law Bulletin*. <https://iris.unito.it/retrieve/handle/2318/1742871/620624/cardozo%20commons.pdf>
- Vergara C. (2020). *Systemic corruption: constitutional ideas for an anti-oligarchic republic*. Princeton University Press. <https://press.princeton.edu/books/hardcover/9780691207537/systemic-corruption>
- World Bank and World Health Organization. (2017). Half the world lacks access to essential health services, 100 million still pushed into extreme poverty because of health expenses. *World Health Organization*. <https://www.who.int/news/item/13-12-2017-world-bank-and-who-half-the-world-lacks-access-to-essential-health-services-100-million-still-pushed-into-extreme-poverty-because-of-health-expenses>
- World Health Organization. (2016). *Towards improving access to medical devices through local production. Report of a case study in four sub-Saharan countries*. <https://www.who.int/publications/i/item/9789241510141>