

# Environmental Protection for the 21<sup>st</sup> Century: Putting Equity at the Top of the Agenda

# Advanced Manufacturing Technologies (AMT): Applications for Equitable Environmental Protection

As a theme, *advanced manufacturing* contains a broad and interdisciplinary suite of technological capabilities. While the text below highlights a few select areas of interest (synthetic biology, additive manufacturing, and nanotechnology), this list is certainly not representative of the full scope of advanced manufacturing technologies and their applications. However, we present some forward looking technologies as rich areas for further exploration with regards to opportunities and critical characteristics for advancing environmental and economic equity.

Advanced manufacturing technologies (AMT), as a broad category, involves multiple scientific and engineering disciplines that cross industries. This is a vast, complex, and ever-evolving area of research. For the present discussion, we begin to explore how the future of manufacturing is connected to the future of equitable environmental protection. Industrial manufacturing processes, while supremely important to global economics and the sources of countless innovations contributing to modern living, are also characterized by environmental externalities—the undesirable side-effects of production. We propose that the implementation of some advanced manufacturing approaches can mitigate such side-effects, including environmental health risks and climate change, while improving our utilization of resources (e.g., energy, natural resources, and land).

While some advanced manufacturing may be generally related to robotics and automation, here we focus specifically on technologies related to novel material science and select engineering concepts that may become enablers of decentralized manufacturing. By decentralized, we simply mean supply chains that are designed to produce goods at smaller scale, and perhaps in a more customizable "on demand" fashion, in places where traditional manufacturing practices may not be feasible or desirable. These places may be physical, for example, placement of a manufacturing site closer to a new type of fibrous feedstock, but such *places* may also be economic in nature. For example, AMT may facilitate new opportunities in certain sectors of the market that have historically relied on traditional manufacturing; for example, construction may

be able to evolve toward more vertically integrated supply chains with on demand machining/printing of select building components. Perhaps, some future forms of manufacturing will lessen the occurrence of the *not in my backyard (NIMBY)* problem, which is often associated with traditionally dirty production processes and waste streams, including energy infrastructure.

Below, we briefly explore three initial technological areas selected for potential in both scientific advancement and improved environmental profiles: additive manufacturing, nanotechnology, and synthetic biology. We then propose examples that imagine how these innovation areas may lead to more equitable environmental outcomes. We also highlight the need for public policy to facilitate and moderate technological advances along the way to ensure equitable outcomes. Ultimately, our hope is that knowledge of advanced manufacturing leads to progressive management of natural environments and maximization of benefits for the diverse communities living within them. We argue that more *sustainable* technologies will lead to production of safer materials, improved energy management, and reduced greenhouse gas (GHG) emissions, amongst other societal benefits.

### **Select Technologies Defined**

Citing sources from the late 1980s and early 1990s, McDermott and Stock (1999) describe defining characteristics of AMT mostly related to computer-driven automation.<sup>1</sup> The OECD definition echoes this. Such definitions appear too narrow for AMT of the 21<sup>st</sup> century or the fourth Industrial Revolution (4IR). A broader and more forward-looking characterization of AMT might entail the use of a combination of novel feedstocks, material science, biomimicry, biological processes, and precision automation to produce new solutions to societal needs. The public-private partnership "institutes" of *Manufacturing USA* offer insight into the array of technologies that fall under the umbrella term AMT.<sup>2</sup> AMT may offer "lean" and "agile" manufacturing solutions, but also versatile innovations that are beyond the scope of simply information technology (IT) facilitated production. A selection of AMT innovation areas with potential links to environmental protection are highlighted below.

#### 3D Printing (Additive Manufacturing)

Three-dimensional (3d) printing technology is a form of additive manufacturing, which broadly entails layering of various, sometimes novel, materials to create structural matrices through a computer-guided printing process.<sup>3</sup> Once thought of as a costly process reserved for rapid proto-typing, the 3d printing sector has reached a stage of producing not only prototypes, but also commercialized end-products.<sup>4</sup> At least in theory, this design and manufacturing method offers desirable flexibility and "just-in-time" (i.e., on demand) capabilities for some

<sup>&</sup>lt;sup>1</sup> McDermott, C. M., & Stock, G. N. (1999). Organizational culture and advanced manufacturing technology implementation. *Journal of Operations Management*, *17*(5), 521-533. <sup>2</sup>See: https://www.manufacturingusa.com/institutes

<sup>&</sup>lt;sup>3</sup> Rejeski, D., Zhao, F., & Huang, Y. (2018). Research needs and recommendations on environmental implications of additive manufacturing. Additive Manufacturing, 19, 21-28.

<sup>&</sup>lt;sup>4</sup> Murr, L. E., & Gaytan, S. M. (2014). Advances in additive manufacturing and tooling. *Comprehensive Materials Processing*, 135-161.

manufacturing applications. For example, in response to a spike in demand, a good may be designed digitally in one market for rapid production in another market that has a printer in lieu of a traditional, scaled manufacturing site. Such technology may also provide solutions in some markets where physical distribution is problematic, perhaps due to a lack of transportation infrastructure such as roads and railways, or in times of supply chain disruptions. The scale of 3d printed capabilities ranges from micro, as in the case of some medical applications such as biological tissue printing, to macro as seen in automotive and some concrete construction applications. The idea of just-in-time manufacturing reduces energy and material waste associated with supply chain overproduction.

One recent review notes advancement in biomedical solution printing using layered, additive manufacturing principles. The authors emphasize the promise of this technology to solve tissue and organ donation problems for time sensitive medical needs, though key limitations still exist such as achieving sustained cell nutrition in the printed matrices.<sup>5</sup> It is acknowledged that further study is necessary to achieve improved and novel 3d printing feedstocks—an area that presents opportunities for solutions from the field of synthetic biology. Moving toward large scale 3d printing applications, recent review articles indicate progress and potential sustainability in durable goods manufacturing and building construction applications. Notably, as technologies continue to advance, this area may be challenged by a lack of local regulatory attention.<sup>6</sup> For example, building codes may first need to be reassessed in order to realize benefits from additive construction. However, some concepts for 3d printed buildings are, in fact, entering the marketplace.<sup>7</sup>

#### Synthetic Biology

Definitions of synthetic biology vary in complexity in the literature. Agapakis (2014) provides a concise definition, "the application of engineering design principles to biology."<sup>8</sup> Cameron et al.'s (2014) description refers more specifically to "forward-engineer[ing] cellular behavior."<sup>9</sup> And the United Nations categorizes synthetic biology as a sub-category of biotechnology based on definitions outlined by the Convention on Biological Diversity and the Cartagena Protocol on Biosafety.<sup>10</sup> Essentially, this area of research involves identifying and

<sup>7</sup> See: <u>3-D-printed homes: A concept is turning into something solid</u>

<sup>&</sup>lt;sup>5</sup> Yan, Q., Dong, H., Su, J., Han, J., Song, B., Wei, Q., & Shi, Y. (2018). A review of 3D printing technology for medical applications. *Engineering*, *4*(5), 729-742.

<sup>&</sup>lt;sup>6</sup> El-Sayegh, S., Romdhane, L., & Manjikian, S. (2020). A critical review of 3D printing in construction: benefits, challenges, and risks. Archives of Civil and Mechanical Engineering, 20(2), 1-25. and Al Rashid, A., Khan, S. A., Al-Ghamdi, S. G., & Koç, M. (2020). Additive manufacturing: Technology, applications, markets, and opportunities for the built environment. *Automation in Construction*, *118*, 103268.

<sup>&</sup>lt;sup>8</sup> Agapakis, C. M. (2014). Designing Synthetic Biology. *ACS Synthetic Biology*, *3*(3), 121–128. <u>https://doi.org/10.1021/sb4001068</u>

 <sup>&</sup>lt;sup>9</sup> Cameron, D. E., Bashor, C. J., & Collins, J. J. (2014). A brief history of synthetic biology. *Nature Reviews Microbiology*, *12*(5), 381–390. https://doi.org/10.1038/nrmicro3239.
<sup>10</sup>See: Synthetic Biology | Department of Economic and Social Affairs (2015)

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manipulating biological "functional elements" in useful ways that alter the outputs or functionality of living organisms.<sup>11</sup>

The suite of synthetic biology technologies may be utilized in numerous applications thought to result in environmentally favorable outcomes. Current and potential applications include efficient and safe waste treatment, crop nutrient delivery, protein and other food creation, pollution remediation, and consumer product manufacturing (e.g., packaging, fibers, drugs, and cosmetics). Because of the myriad potential applications for synthetic biology, we have also created a separate, complementary background paper specifically on this technology area.

### Nanotechnology

Nanotechnology is the application of nanoscience enabling a sweeping array of technologies at a very small scale of approximately 10<sup>-9</sup> meters—a *nanometer*—or smaller. Nanomaterials are simply materials (e.g., a chemical structure) with dimensions at the nanometer scale (see ISO/TR 18401:2017).<sup>12</sup> Such materials and "objects"—perhaps even existing within another nanomaterial structure—are desired for their unique physical and chemical properties, or modes of action, which may alter how certain materials function or react under very specific conditions including within the human body. Such properties are leveraged by researchers and industries across a wide range of applications, from filtration to conducting electricity with specialty chemicals, such as solar paint.<sup>13</sup> Notably, it is often the surface structure or surface area of this class of advanced substances that is extremely desirable.

### Imagining Social, Environmental, and Economic Impacts

Conceptualizing the future of manufacturing across multiple industries involves imagining technological advances that enable production efficiencies at least comparable to those in the marketplace today but with relatively fewer environmental harms. Since it is well documented that such environmental harms can affect human health, and those effects may be most intense in certain marginalized communities, we draw connections between advanced manufacturing technology and the field of environmental justice.<sup>14</sup> Let us imagine, for example, the decision-making process for permitting a new industrial site. Whether it be for an electric power, pharmaceutical, or food production facility, the area around the site is likely to experience some impacts. Traffic patterns may change, water and energy demand may increase, as will the volume of wastewater entering the local sewer system. In some cases, noise and air pollution may increase—not only in the form of air toxics or particulates, but potentially also in the form of nuisance odors. Some of the technologies included in the umbrella category of advanced manufacturing—including those outside the three areas of interest defined above—may offer

<sup>&</sup>lt;sup>11</sup> Bagley, Margo. Digital DNA: The Nagoya Protocol, Intellectual Property Treaties, and Synthetic Biology. Synthetic Biology Project. December 2015.

<sup>&</sup>lt;sup>12</sup> ISO nanotechnology definitions: <u>TR 18401:2017(en)</u>, <u>Nanotechnologies — Plain language explanation of selected</u> terms from the ISO/IEC 80004 series

<sup>&</sup>lt;sup>13</sup> Shatkin, J. A. (2017). *Nanotechnology: health and environmental risks*. CRC Press.

<sup>&</sup>lt;sup>14</sup> For a salient example of the link between polluting facilities and communities characterized by indicators of social deprivation, see Cushing et al. (2018): <u>https://doi.org/10.1371/journal.pmed.1002604</u>

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promising new ways to achieve the desired industrial output without (or with reduced) undesirable side effects.

Enabled by synthetic biology, computer science, and artificial intelligence (AI), the futuristic power station—either standalone or built specifically to support another type of industrial site—may generate energy in cleaner ways. Specialized microorganisms could serve as catalysts to increase the efficiency of the conversion of solar energy to a burnable biofuel by algae without the emissions of fossil fuel derived energy. Or perhaps, conventional hydrocarbon cracking stacks used in the production of specialty chemicals can be replaced by relatively benign, innovative bioreactor processes in which the same chemical compounds are produced via fermentation with genetically engineered yeasts. These currently hypothetical process innovations, once scaled, may contribute to greater equity in outcomes due to more precise design and engineering that can mitigate some of the pollution from conventional manufacturing. The communities surrounding such sites may be spared from the health risks while still benefiting from job creation and locally produced goods. With this future state of manufacturing, corporations may find they have fewer hurdles to jump along the way when planning where to make capital investments in new facilities. If a corporation is able to provide evidence of a relatively safe, non-obtrusive production process, their environmental impact assessment will be less cumbersome. In fact, some states have passed environmental justice legislation in recent years that may incentivize corporations to innovate their production methods because conventional processes will be more frequently scrutinized in the permitting process. State law S232 in New Jersey (2020) is a prime example.<sup>15</sup> This bill requires environmental justice impact assessments, distinct from environmental impact evaluation, with the specific intention of preventing environmental inequities from new industrial permits.

# New Jersey State Law S232<sup>16</sup>

This environmental justice law is "an act concerning the disproportionate environmental and public health impacts of pollution on overburdened communities." Declaring "that no community should bear a disproportionate share of the adverse environmental and public health consequences." Passed in 2020, this law requires the state of New Jersey to publish an online list of overburdened communities and adds permitting requirements for industrial sites. Of note is the requirement for environmental justice impact statements (EJIS). S232 also defines environmental or public health stressors, which may factor into industrial restrictions during zoning or permitting in the future.

 <sup>&</sup>lt;sup>15</sup> Office of the Governor | Governor Murphy Signs Historic Environmental Justice Legislation
<sup>16</sup> <u>Title 13. Chapter 1D. Part XI. (New) Overburdened Communities §§1-5 - C.13:1D-157 to 13:1D-161 PL 2020,</u> CHAPTER 92, approve; New Jersey governor signs law aimed at protecting poor from pollution

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Srai et al. (2016) provide a robust and optimistic overview of multiple distributed manufacturing opportunities.<sup>17</sup> In theory, distributed manufacturing could be one way that corporations work with the public sector on market-based approaches to stimulate local or regional economies; for instance, in response to the declining coal sector. Supply chains may become more agile and production of goods may more easily take place closer to demand centers or closer to the key raw material sources.<sup>18</sup> Additionally, the literature notes the possibility of distributed manufacturing working synergistically with circular economy concepts (e.g., closed loop systems that re-use some forms of waste as production inputs).

The potential for integrating AMT with new plans for economic stimulus (at federal, regional, and state/local levels) should not be underestimated. New manufacturing centers may replace industries of the past while also helping companies enter new markets. Some rapidly developing economic areas, including nations outside of the U.S., are likely sources of new customers (future demand). Perhaps manufacturing companies and entrepreneurs can leverage smaller-scale AMTs to enter such markets. For example, the international food conglomerate Nestle has investigated how smaller-scale, modular manufacturing investments may facilitate entering new markets.<sup>19</sup> Smaller, modular manufacturing concepts could have many benefits, especially when one considers how 3d printing technologies may be utilized in manufacturing modular building components and machining replacement parts. More generally, additive manufacturing may facilitate the growth of modular construction manufacturing centers for residential homes. Such homes may be designed with novel materials, highly efficient resource use, less waste, and drastically shorter construction timelines (some warehouse built modular home projects are built indoors and not subject to weather delays). Of course, the implementation of additive manufacturing innovations will ultimately show us if some of the favorable possibilities, such as relative environmental benefit over a legacy manufacturing process, are easily attainable. Negative side-effects or unforeseen consequences—such as promotion of short-use 3d printed consumables or new forms of polymer pollution-may be observed. Corporations and researchers will need to consider life-cycle analysis thinking, including assessment of energy input requirements, before determining whether novel additive manufacturing concepts actually help realize net benefits over current processes and technologies (see Rejeski et al., 2018 and Ribeiro et al., 2020).<sup>20</sup> Additionally, sustainability certifications such as the US Environmental Protection Agency's (EPA) "design for environment" programs as well as international standards may need to be adapted to consider environmental and health outcomes associated with new AMTs, such as 3d printed buildings.

Beyond selling to new customers, distributed manufacturing can spark more localized factor markets, like an industrial ecosystem of new supply chain actors, that evolve to meet

 <sup>&</sup>lt;sup>17</sup> Srai et al. (2016) Distributed manufacturing: scope, challenges and opportunities, International Journal of Production Research, 54:23, 6917-6935, DOI: 10.1080/00207543.2016.1192302.
<sup>18</sup> See: Srai et al., 2016

<sup>&</sup>lt;sup>19</sup> Nestle Introduces Flexible. Simple and Cost-Effective Modular Factories

<sup>&</sup>lt;sup>20</sup> Ribeiro, I., Matos, F., Jacinto, C., Salman, H., Cardeal, G., Carvalho, H., ... & Peças, P. (2020). Framework for life cycle sustainability assessment of additive manufacturing. *Sustainability*, *12*(3), 929.

business-to-business demand for goods and services in a new locale. We might imagine that new, high-tech and/or bio-tech industrial zones—next generation economic enterprise zones—could develop near new, micro manufacturing sites and novel feedstocks. We envision investment in *clean-tech* operations that mimic and improve upon existing industries. For example, the corn ethanol industry in the American Midwest has resulted in ethanol-specific refining site development near farms that choose to plant ethanol-specific corn varieties (as opposed to food/feed grade varieties). *What will future feedstocks and biofuel production look like?* 

Secondly, one feature of recent tax policy changes in the U.S. has been capital gains deferment (and reduction) incentives for real estate development in so-called *opportunity zones*. Given the prospect for future manufacturing sites to be less environmentally risky, such opportunity zones might support new manufacturing enterprises in the future without causing environmental justice issues observed from urban planning failures of the past.

In parallel to the developing economic case for advanced, distributed manufacturing, vocational training institutions such as community colleges may find that adapting curricula to teach advanced manufacturing skills is necessary and impactful to facilitate an area's economic transition. National Public Radio (NPR) recently highlighted the Symbol training center (Chicago) for their advanced manufacturing training programs.<sup>21</sup> The type of economic ecosystem that might develop as a result of high-tech distributed manufacturing may prove more valuable than the sum of its individual parts. The high-tech Florida "space coast," which created a German-style apprenticeship partnership, offers another example of a workforce development model.<sup>22</sup> Finally, related to this workforce side of the future of manufacturing is the idea that new, and possibly more distributed, manufacturing zones may affect the dynamics of how people get to work. Since a small decline during the Great Recession, U.S. commuting times have gradually ticked upward.<sup>23</sup> Longer commuting times, especially in passenger vehicles, leads to more vehicle emissions and reduced quality of life for some workers. With less centralized manufacturing, some industrial sites will be able to be safely placed closer to workers, perhaps reducing commuting distances and mitigating transportation externalities, at least for some people.

Of course, assuming that select advanced and distributed manufacturing concepts prove to be instrumental in reducing environmental risks from modern production, such technologies will also need to demonstrate the possibility of balancing environmental benefits and economic returns. Especially in some sectors, the transition to more distributed manufacturing will likely be very slow as business models must be reimagined after decades of striving to maximize economies of scale in current production processes. Some distributed manufacturing business plans will likely offer a different timeline to realizing returns on investment compared to the status quo. Investors and business strategists may find it necessary to adjust their time horizons.

<sup>&</sup>lt;sup>21</sup> U.S. Manufacturers Can't Find Enough Skilled Workers To Fill Open Jobs

<sup>&</sup>lt;sup>22</sup> Space Coast Consortium

<sup>&</sup>lt;sup>23</sup> Burd, C., Burrows, M., and McKenzie, B. Travel Time to Work in the U.S.: 2019. U.S. Census Bureau American Community Survey Reports. March 2021.

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Similar to investments in renewable energy assets, increased capital expenditure may be required upfront, but the investments may still be worthwhile when one considers lower operational costs in the long run (perhaps due to lower feedstock, energy, or logistical costs).

#### Conclusions

Future-looking manufacturing techniques and technologies offer promising opportunities for industrial sectors to continue to grow with fewer inequitable environmental outcomes. Broadly, new manufacturing technologies, such as processes based on synthetic biology, may be found to produce goods with less pollution for surrounding communities. However, regulation is still necessary to help guide the private sector in its pursuit and utilization of novel technologies at scale. In brief, the literature and experts indicate a need for transparency as technologies mature and enter the marketplace. In part, this is to avoid fear and misconceptions from consumers about new technologies. Widespread familiarity, yet limited understanding, of genetically modified crops serves as a relevant, cautionary example of a scientific advancement that has faced stakeholder pushback. Beyond citizen acceptance, tax incentives, urban planning/zoning, and public transportation policies may also be designed to create a favorable environment for investment in the future of manufacturing. Mohai et al. (2009), in their review on environmental justice, note certain policy measures that could complement advanced manufacturing; for example, mandates for green procurement and clean production tax breaks.<sup>24</sup>

In some cases, especially as the technologies discussed above continue to show evidence of scalability and improved risk profiles for investment, advanced manufacturing techniques may be able to reduce costs relative to comparable conventional industrial processes. Even cost parity coupled with fewer environmental externalities may be considered a cost reduction achievement. In some sectors, research and development in AMTs will lead to technical processes that could unlock so-called *green growth*. Corporations may be able to adjust their manufacturing processes to be relatively environmentally benign while also hitting their financial targets. Moreover, such companies may find it possible to reassess long-term plans to enter new markets that previously lacked manufacturing infrastructure (e.g., lack of roads or utilities). This could then result in positive local labor market outcomes, changes in where natural resources are processed/consumed, shorter transportation distances, as well as changes in whether and the extent to which waste and pollution are generated.

Below, we highlight the COVID-19 vaccine case as an example of synthetic biology enabled production. While this example may not offer direct benefits for the environment, the novel vaccine technology used in some COVID-19 vaccines is illustrative of how AMT, specifically synthetic biology, may impact health equity. Of course, the logistics of vaccine distribution have been accompanied by criticism about waste. In some areas, excess, unused vaccines are thrown away daily, all while other locales (and entire nations) lack access. In a hypothetical open-source distribution model of the future, AMT may enable localized vaccine production that increases access while also reducing waste.

<sup>&</sup>lt;sup>24</sup> Mohai, Paul, Pellow, David, and Roberts J. Timmons. Environmental Justice. Annual Rev. Environment and Resources. 2009. 34:405-30.

#### **Use Case: Vaccine Technology**

Many aspects of the global public health response to COVID-19 have highlighted that nations were wholly unprepared for a pandemic, despite previous threats. However, one integral category of preparedness—vaccine technology—stands out as a success story. It has become evident to the world that vaccine technology has not stood still over the last century. The initial COVID-19 vaccines, produced using messenger ribonucleic acid (mRNA) technology, are based on decades of biomedical research progress, which facilitated an unprecedented short timeline to market. Still, we saw a need for the technology owners in the private sector to interact with political forces in the public sector to expedite regulatory approval, scale manufacturing, and coordinate rollout. Partly a result of this bureaucratic process, the distribution of the vaccine, distinct from its development, leaves much to be desired. Of course, the politicization of the public health crisis overall has also affected citizen acceptance of the new vaccine. Below, we briefly explore the technology, equity concerns, and policy implications of the COVID-19 vaccine case.

#### Technology Overview

Numerous biomedical techniques exist that may be utilized to develop a vaccine. For example, the famed polio vaccination was developed during the 1950s using viral strains harvested from laboratory animals infected with polio viruses. Polio vaccines involved two different strategies, one with inactivated virus and another, taken orally, with attenuated-or weakened-viral strains. These vaccines vary in formulation, side-effects, and characteristic immune response.<sup>25</sup> Whereas historically vaccine production involved growing the target pathogen, the advanced mRNA technology that has developed more recently produces vaccine synthetically, based on our advanced understanding of a pathogen's (i.e., the virus') genetic makeup—the genome. Today's coronavirus vaccines also take advantage of nanotechnology in the form of nano-scale liposome encapsulation of mRNA, which then acts as a synthetic biology factory within host cells. The mRNA directs development of proteins, known as antigens, that induce the desired immune response in reaction to the presence of viral cells.<sup>26</sup> Importantly, the genetic messaging "tool" that teaches the human immune system about the unique COVID-19 "spike" protein quickly degrades without entering the cell nucleus, thus preventing perpetuation of any altered genetic material within the body.<sup>27</sup> By employing this knowledge of genetic engineering to develop vaccines, we move closer to a situation in which prophylactic tools to fight disease are more "on demand," as described by Maruggi et al. in their 2019 review. Future innovation may come from further leverage of AI tools to rapidly analyze genetic sequences and predict viral

<sup>27</sup> What Stops the Body from Continuing to Produce the COVID-19 Spike Protein after Getting an mRNA Vaccine?

<sup>&</sup>lt;sup>25</sup> Baicus A. (2012). History of polio vaccination. *World journal of virology*, 1(4), 108–114. <u>https://doi.org/10.5501/wjv.v1.i4.108</u>

<sup>&</sup>lt;sup>26</sup> Thomas Schlake, Andreas Thess, Mariola Fotin-Mleczek & Karl-Josef Kallen (2012) Developing mRNA-vaccine technologies, RNA Biology, 9:11, 1319-1330, DOI: <u>10.4161/rna.22269</u>; Maruggi, G., Zhang, C., Li, J., Ulmer, J. B., & Yu, D. (2019). mRNA as a transformative technology for vaccine development to control infectious diseases. *Molecular Therapy*, *27*(4), 757-772.

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variants, which can then inform vaccine research and production. When this technology is combined with principles of open-source science, we can envision a future state in which digital vaccine blueprints can be sent electronically for distributed production in biomedical laboratories around the world.

## Equity Concerns

The initial vaccine rollout in the United States primarily sought to reach the most elderly and key frontline response personnel, namely healthcare workers. From one perspective, this is a logical and rational approach aimed at vaccinating the age demographic observed to be most vulnerable to the virus (i.e., highest death rate population), as well as those called upon to treat patients seeking medical care. Of course, this is unidimensional. When one considers other demographic characteristics, such as socioeconomic status (SES) and race/ethnicity, the notion of equitable distribution and risk prioritization becomes a more complicated normative question. Some individuals and communities in our population may have higher risk because of preexisting health concerns unrelated to age. Some such health concerns are not directly related to individual choices, of course. For instance, there is a literature that connects SES with disease burden, sometimes associated with environmental health risks (for example, see Persico, 2020).<sup>28</sup> Yet another approach to vaccine distribution could involve basing strategy on the sub-populations thought to be most at-risk of spreading disease: those residing in institutionalized settings and more front-line workers such as first-responders, public transportation employees, and food service operators. Between these approaches, politicians, economists, health practitioners, and citizens may disagree. Vaccine rollouts are also subject to logistical challenges connected to equity. For example, some rural communities-especially considering political, information access, and vaccine hesitation factors-have not been efficiently reached due to low demand and transportation distance from vaccine service providers. The ultimate judgement of whether such a nation's rollout was equitable may not be determined for years-until sufficient analysis of empirical evidence has been conducted.

Ultimately, different stakeholder groups will arrive at various conclusions in response to this question. The U.S. Centers for Disease Control and Prevention (CDC) acknowledge the variety of factors associated with COVID-19 and health inequities, including overrepresentation of certain minority groups in jobs considered to be "essential" as well as healthcare access disparities.<sup>29</sup> Beyond the U.S. context, nations appear to be attempting to balance risks between types (and producers) of vaccines and the realities of overwhelmed hospital systems. As of spring 2021, India had emerged as a striking and tragic example of a nation with extreme shortage of medical oxygen and low vaccine availability, despite pharmaceutical manufacturing assets.

# Policy Implications

<sup>&</sup>lt;sup>28</sup> Persico, C. (2020). Can Pollution Cause Poverty? The Effects of Pollution on Educational, Health and Economic Outcomes. *Health and Economic Outcomes (February 12, 2020)*.

<sup>&</sup>lt;sup>29</sup> Health Equity Considerations and Racial and Ethnic Minority Groups

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While the time-to-market may be greatly reduced in future vaccine development cases, as has been the case for coronaviruses through 2019 and 2021, regulators play a moderating role in how quickly new vaccines (or, more broadly, medical technologies) reach patients. Many would agree that allowing unchecked entry of new advanced biomedical technologies into the marketplace would be risky, perhaps leading to governance failures. However, if regulation is not balanced, there may be a point at which precaution, despite good intentions, can impede technological progress. For example, in the case of nanotechnology, regulatory precautions in the face of uncertainty over the potential for novel health and environmental risks dramatically slowed adoption of nanoscale materials and technologies in many consumer facing markets. The lessons from the nanotechnology case provide rationale for more rapid and targeted investigation of emerging advanced technologies, and for policies to be more adaptive and responsive to innovation, while still protecting health and the environment.<sup>30</sup>

Presently, the COVID-19 vaccine technology response (distinct from the political response), enabled by advanced knowledge of genetics and mRNA vaccine technology, appears to be a success story overall. This case may inform future, perhaps proactive, investment in increasing pandemic resilience. At least in the U.S., the well-studied technology has paired nicely with policy controls to ensure safety through rapid medical trials and production scale-up. It appears that the regulatory approval process controls were effectively preserved to balance risks and rewards, though the politicization of this public health response provides us with a cautionary tale about public sentiment of novel vaccines.<sup>31</sup> The utilization of mRNA technology may also draw more attention toward other useful public health pursuits, including research innovations into cancer and human immunodeficiency virus (HIV) solutions.<sup>32</sup>

Like the public health data about the disease itself, our knowledge of the ultimate vaccine effectiveness in preventing illness and reducing the spread of the virus—especially the spread of variant strains—is still nascent. However, the use case of synthetic biology for vaccine production is useful to highlight opportunities and equity concerns related to advanced manufacturing technologies. Moreover, since some vaccines entering the market do not utilize mRNA technology (e.g., Johnson & Johnson), scientists will ultimately be able to compare and contrast these valuable public health tools and technologies.

<sup>&</sup>lt;sup>30</sup> Shatkin, J. A. (2020). The future in nanosafety. American Chemical Society.

<sup>&</sup>lt;sup>31</sup> <u>COVID-19 Vaccine Approval Process Overview</u>

<sup>&</sup>lt;sup>32</sup> Mu Z, Haynes BF, Cain DW. HIV mRNA Vaccines—Progress and Future Paths. Vaccines. 2021; 9(2):134. https://doi.org/10.3390/vaccines9020134

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