21st Century Capitalism and Innovation for Health

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Key words: financialization, medical devices, the US Food and Drug Administration, pharmaceuticals, regulation, digital health, intellectual property

Abstract

21st century capitalism undermines health outcomes in myriad ways. Structural economic changes have had negative effects on medical innovation and public health and are poorly aligned with social goals. Key features of the contemporary political economy include both monopoly capitalism, based upon stringent intellectual (IP) protection that suppresses economic competition, and Wall Street capitalism, or financialization, that prioritizes value extraction over value creation to maximize shareholder value. One can see the impacts of these features by examining contemporary trends in the pharmaceutical industry, the production of COVID-19 response essentials such as ventilators and personal protective equipment (PPE), the rise of digital health, and regulatory change over time.

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Since the late 1970s the US has promoted policies promoting competitiveness on global markets and innovation as the most efficient strategies for creating jobs and generating wealth. Public sector economic policies promoted technology-based ventures and took steps to facilitate the private funding of scientific and technological innovation. The notion of innovation as a means to generate wealth stands in contrast to a notion of health innovation 'as changes that allow higher-quality products at competitive cost to emerge and be diffused' (Mazzucato and Roy, 2019, p. 102). If we conceive of the goal of public health innovation as addressing "unmet health needs globally" and delivering therapeutic advances that are affordable and accessible to all" the current system is failing (Torreele, 2016: 2). As the following sections demonstrate, in both financing and regulation 'health policy outcomes (e.g. patient safety, quality-adjusted life years, cost savings etc.)' often take a back seat to wealth generating priorities (Lehoux et al., 2017c, p. 510).

21st century capitalism is not the "neoliberalism" of the Reagan and Thatcher 1980s. 21st century capitalism is less about privatization and liberalisation than it is about

financialization, monopoly and monopsony power, and the concentration of wealth. It prioritizes value extraction over value creation, and features, "increasing political and economic power of banks and the rentier class (rentiers are those who live off income from investments in property or securities rather than from producing anything)" (Braithwaite, 2019: 559). In the 1950s financial profits made up just 10 percent of U.S. GDP but surged to nearly 40 percent by the early 2000s (Braithwaite, 2019: 559-60). Tulum and Lazonick argue that "the tension between innovation and financialization becomes vastly more problematic when the company is governed for the sake of financial interests who have the power to extract far more value for themselves than they have contributed to the value-creation process" (2018: 283). This outsized role of finance in contemporary capitalism has skewed incentives away from innovation for public health purposes and regulation for patient safety.

Economic policy establishes the broader parameters – incentives for and constraints on innovation for health. If we look at the global economy from 30,000ft we can identify profound structural change. Beginning in the late 1970s and 1980s the leading world economy, the United States, pivoted to a knowledge- and services-based economy. A knowledge- and services-based economy relies upon intangible assets such as intellectual property (patents, copyright, trade secrets) and financial instruments (e.g., derivatives, securities). Owners of intangibles have incentives to reduce their physical footprints, labor and real estate, to maximize profits on a much smaller set of physical assets (Schwartz, 2017, p. 209). Owners of intangibles can capture the lion's share of the added value of a product in part due to the exclusive nature of intellectual property. For example, Apple's iPad is manufactured in China; its manufacturer received just ten dollars in direct payments for wages per iPad – or 1.8 percent of the product's value (Tusikov, 2016: 9). Patents, in particular, are key components of successful pharmaceutical and medical device product businesses (Mas, J-P. and Hsueh, B. 2017, p. 184). For example, the US-based firm 3M owns multiple patents on the N95 masks that are in high demand and short supply in the global coronavirus pandemic. The ability to exclude others from using a firm's intellectual property (IP) ensures higher profits for the firm than would be realized in a fully competitive market in which multiple firms had access to that IP.

In the late 1970s and 1980s, US-based IP owners lobbied for regulatory and legislative reform to expand IP protections. Lobbyists deployed the rhetoric of "competitiveness" and "innovation". Distinguishing their industries from those of declining rustbelt sectors, they successfully argued that IP-based industries such as pharmaceuticals, music, movies, information technology and computing were the export- and profit-generating wave of the future. Thereafter the US pushed for these sectors' interests in a number of forums, including trade negotiations, and saw them as sources of American comparative advantage in global markets. By 1994 IP owners had succeeded in globalizing their preferences through the Agreement on Trade-Related Intellectual Property Rights (TRIPs) in the World Trade Organization (Sell, 2003).

TRIPs ushered in a new era of "intellectual monopoly capitalism"; IP owners seek to avoid competition (Pagano, 2014). Less competition means higher prices. Strategic behavior aimed at blocking generic competition contributes to rising drug prices; "companies create serial barriers to hold off competition" (Feldman, 2018: 7). Evergreening is a prominent

strategy in the pharmaceutical industry; drug companies can get new patents (therefore, extensions on monopoly pricing) on re-tooled versions of about-to-expire drugs by changing the formulation from a tablet to a gel cap for example. As Feldman points out, "when more than 70% of best-selling drugs had their protection extended, it is clearly the go-to approach for profitability" (2018: 49-50). Patent protection increases the price of drugs and reduces access to medicines and vaccines.

This pro-IP agenda coincided with a pro-Wall Street agenda that facilitated the globalization of finance and increased the economic and political power of the financial sector. As Tyfield suggests, the global economy shifted "from a cycle of strong growth spread across the economy and led by productive business to one in which the economy is dominated by the financial sector" (2008, p. 554). For instance, in 1975 one-sixth of the Standard and Poor's top 500 companies represented the value of intangibles; in 2015 that figure was five-sixths (Medhora, R. P., 2018, p.2). Financialized capitalism is 'a pattern of accumulation in which profits accrue primarily through financial channels rather than through trade and commodity production' (Krippner, 2005, p. 174). Increasingly financial markets, motives, institutions and elites have come to dominate the global political economy affecting everything from production, consumption, regulation and health (Epstein, 2005). Financialized capitalism has dramatically increased the power of private capital vis-à-vis the public sector, exacerbated inequality and economic concentration. Key financial actors are retail and commercial banks, hedge funds, asset management firms, venture capitalists, insurance companies and pension funds (Busfield, 2020, p. 1).

Financialized capitalism is also predicated on maximizing shareholder value. Investors in shares in firms expect that a firm's profits will increase the rate of return on their investment. Shareholder value is assessed quarterly, biasing decisions toward short-term gains. As Durand and Milberg point out, 'US firms in particular have had high levels of profit and cash flow in the past 15 to 20 years associated with a disproportionately large payout to shareholders in the form of dividends and share buybacks and sluggish investment' (2018, p. 34). These structural changes have been accompanied by a reduction in public sector funding and a greater reliance on market mechanisms to deliver social goods. At the same time, the growing power of financial markets and shareholder value has reduced the power of labor.

Financial incentives and pharmaceuticals: Wall Street capitalism meets Monopoly capitalism (terms from Braithwaite, 2019).

One can see how financialization changes the behavior of non-financial corporations when examining the pharmaceutical sector (Busfield, 2020: 1). Pharmaceutical innovation substantially has changed as a result of structural economic transformation. In the past, "large, vertically integrated firms carried out virtually all the stages of the drug discovery and commercialisation process, from the discovery of the New Molecular Entities (NMEs) that constitute the active ingredients in medicines to large-scale clinical trials, production and marketing" (Gleadle, et al., 2014: 68). These firms routinely re-invested their profits for in-house R&D, training and retention of skilled employees (Busfield, 2020: 2; Lazonick, 2018). Now industry trends include fragmentation of functions, or vertical disintegration, and a rise in horizontal integration through mergers and acquisitions. The big firms engage

in far less innovation than in the past, and instead seek out firms to acquire that have developed promising pharmaceutical innovations. For example, in 2018 Merck and Pfizer grew large "by acquiring 'blockbuster' drugs [those with at least $1 billion in sales in one year] that other companies have developed and then milking them for revenues over their remaining patent lives" (Lazonick et al, 2019: 4). According to Tyfield, "the importance of the demand from Wall Street for high profit margins in order to maintain share prices has been singled out as a major factor in the futile production of patented and branded me-too drugs by big pharma" (2008: 557). This is an important reason why there are multiple versions of erectile dysfunction and hair loss drugs and a paucity of drugs for lethal afflictions of the poor, particularly in the global south.

Financialization in the pharmaceutical sector has meant "a change in strategic priority from delivering value to customers (in the form of marketable products) to delivering value to creditors and shareholders (in the form of distributable profit or financial instruments saleable at profit)" (Gleadle et al, 2014: 71). The two Tables below illustrate the differences between the integrated and financialized models for both Pharma and Biotech.

Table 1
Strategic priorities under ***integrated*** model (Gleadle, 2014: 71)

	Pharma	Biotech
Priority stakeholders	Customers (doctors, patients, state agencies)	Customers (Pharma companies, independent distributors)
Main product focus	Marketable drugs	Marketable or development-stage drugs
Main performance indicator	Market share, growth rate, patients, new product pipeline	Patents, new products

Table 2
Strategic priorities under ***financialized*** model (Gleadle et al, 2014: 71).

	Pharma	Biotech
Priority stakeholders	Shareholders, bondholders, banks	Pharma partners, other equity and bond holders
Main product focus	Re-tradeable bonds, shares, strategic shareholdings	Re-tradeable shareholdings, development-stage drugs
Main performance indicator	Return on equity, distributable profit, share price	Return on equity, IPO valuation, share price

Under this new financialized model, executive compensation is stock based. Therefore, pharmaceutical and biotech executives are incentivized to boost share prices (Lazonick et al, 2019: 6). For example, in 2016 John C. Martin, CEO of Gilead Sciences, earned $98.4 million, of which 96% was stock-based pay (Tulum and Lazonick, 2019: 294-95). Pharmaceutical companies boost share prices by buying back shares of their own companies on the open

market. Until 1982 share buybacks were illegal. But that year the Securities and Exchange Commission introduced Rule 10b-18, allowing buybacks, which Lazonick has dubbed "a license to loot" (2018). Instead of investing in productive activities, the "downsize-and-distribute resource-allocation model" shifts resources to "unproductive financial activities that benefit senior managers, shareholders and the financial sector" (Busfield, 2020: 2; also see Lazonick, 2018). In 2019 institutional investors such as BlackRock, Vanguard, and State Street were the majority shareholders in pharmaceutical firms with holdings percentages ranging from 68-80% (Busfield, 2020: 3).

Today the bulk of pharmaceutical firms' profits are used to buy back shares to drive up stock prices and distribute dividends to shareholders. Between 2009 and 2018, 18 of the pharmaceutical firms publicly listed on the S&P Exchange had combined profits of $588 billion; they spent $335 billion on buybacks and $287 billion on dividends (Lazonick et al, 2019: pp. 3-4). Some of the consequences of this focus on share price include a short-term orientation (performance is measured quarterly), higher prices for pharmaceutical products to pay for buy backs and dividends, higher marketing costs, less money for R&D and the development of new drugs, and increased pressure to cut production and manufacturing costs (Busfield, 2020: 4).

Pandemic response: Personal protective equipment and ventilators

These same structural trends have had negative consequences for the COVID-19 response with shortages of personal protective equipment and ventilators. As COVID-19 ravaged the United States, hospitals faced acute shortages of medical equipment. Personal protective equipment (PPE) and ventilators topped this list and meant the difference between life and death for patients and first responders. Just as in the case of the pharmaceutical sector, the top producers and distributors are committed to monopoly and Wall Street capitalisms to the detriment of public health. Multiple patents on N95 technologies for masks have slowed the rapid production and distribution of this vital PPE. The three largest N95 respirator mask producers, 3M, Honeywell, and Kimberly-Clark have outsourced most of their production to Chinese manufacturers to reduce costs and have also dedicated themselves to maximizing shareholder value (Lazonick and Hopkins, 2020: 2). The country's largest PPE distributor, "McKesson, paid out 115 percent of its profits to shareholders, with 100 percent of profits distributed as buybacks" (Lazonick and Hopkins, 2020: 2).

A lead story in *The New York Times* described the failure of a promising ventilator production initiative and highlighted tensions between the pursuit of health and the pursuit of wealth. Between 2010 and 2019 the US government allocated $13.2 billion in R&D countermeasures for pandemic preparedness (Lazonick and Hopkins 2020). The Biomedical Advanced Research and Development Authority (BARDA) awarded one of its contracts to Newport Medical Instruments, a small company, to produce mobile and easy-to-use ventilators that would be priced at $3,000 (versus typically $10,000) for the Strategic National Stockpile. By all accounts Newport was making excellent progress developing the requested ventilators. Its sole business was producing ventilators and it worked closely with the biomedical research agency. In the early 2010s the medical device industry was undergoing substantial consolidation with mergers and acquisitions, and in 2012 Covidien (a $12billion dollar medical device manufacturer) bought Newport for just over $100 million.

The Newport ventilator project was not a priority for Covidien, and Covidien asked the government for a higher sales price when Newport applied for clearance from the Food and Drug Administration (FDA). As the *Times* reported, 'government officials and executives at rival ventilator companies said they suspected that Covidien had acquired Newport to prevent it from building cheaper products that would undermine Covidien's profits from its existing ventilator business' (Kulish, Kliff, and Silver-Greenberg, 2020). Covidien told the government that the project was not sufficiently profitable for the company and asked the government to cancel the contract. Contemporary financialization can slow the pace of innovation as large research-performing companies buy up "smaller concerns with potentially competing technologies" and amass "intellectual property to satisfy the demands of venture capitalists for tangible collateral" (Graham, 2019: 7).

Each of these cases illustrate that the financialized business corporations have undermined development and delivery of pandemic preparedness essentials (Lazonick and Hopkins, 2020: 1). The *Times* concluded that, 'the stalled efforts to create a new class of cheap, easy-to-use ventilators highlight the perils of outsourcing projects with critical public-health implications to private companies; their focus on maximizing profits is not always consistent with the government's goal of preparing for a future crisis' (Kulish, Kliff, and Silver-Greenberg, 2020). Similarly, BARDA awarded Respironics, a small ventilator producer, a contract, but in 2014 Royal Philips purchased the company and Phillips has yet to deliver on the government's ventilator contract (Lazonick and Hopkins, 2020: 2). The government lost precious time and the case illustrates the poor fit between public health priorities and the quest for profits.

Financing digital health innovation

Digital health includes mobile health and telemedicine. 'Mobile health, or "mHealth" is the use of portable devices such as smartphones and tablets for medical purposes, including diagnosis, treatment, or support of general health and well-being' (Nathan et al., 2014, p. 372). Health information technology includes 'electronic medical records, clinical decision support, mobile medical applications, and any software-driven medical device used in the diagnosis or treatment of disease' (Ronquillo and Zuckerman, 2017, p. 536). Some medical technologies, especially mHealth, are more consumer-facing, whereas others are designed to increase efficiency and accuracy for health care providers (e.g., electronic medical records and clinical decision support).

The promises of new medical technologies are compelling – more accurate monitoring and information; greater efficiency; personalized and precision diagnostics and treatment; and greater equality in access to health care in remote and under-served areas. Innovative medical technologies have offered crucial lifelines in the midst of the COVID-19 pandemic. To increase access to urgent medical care while protecting both health care providers and patients, many states have encouraged patients to access telemedicine services to consult with health care providers remotely. Kinsa Health's smart thermometers have been tracking fevers, getting around 162,000 reports from its thermometers' users daily since COVID-19 erupted in the US (McNeil Jr., 2020). The company's database has tracked daily fever readings and has found a sharp drop in fever incidence only *after* the most restrictive stay-at-home guidance had been implemented. This is crucial information for policymakers

under pressure to ease restrictive guidelines. The World Health Organization sees digital health as offering enormous potential for addressing inequality in health care availability worldwide (WHO, 2020).

While the positive benefits and transformative potential are compelling, often there are misalignments between medical device technology and innovation on the one hand, and public health priorities on the other. In a perfect world health and wealth objectives would mesh seamlessly but, as pharmaceutical sector trends and the ventilator shortage story suggest, at times these two goals can be at odds. Identifying conditions under which the two goals are misaligned to the detriment of public health priorities can highlight possibilities for policy reform.

The rise of private financial capital in social sectors has been a function of resource gaps in public funding as well as 'proactive policies for commercialization' (Hunter and Murray, 2019, p. 1266). In 2017, then-President of the World Bank J.Y. Kim stated that, "'our top priority should be to systematically de-risk both projects and countries to enable private sector financing'" (quoted in Stein and Sridhar, 2018, p. 3). In the past several decades, 'a phase of corporate-oriented healthcare reforms transformed healthcare systems into profitable zones for global capital' (Hunter and Murray, 2019, p. 1267).

Venture capitalists play important roles in the development of medical devices and digital health products. In a knowledge-based economy commercial entities '"seek capital, in the form of speculative investment, to transform [research-based] discoveries into commercial products and services"' (Lehoux, et al., 2017b, p. 206). In 1980 the US Congress passed the Bayh-Dole Act to promote innovation by facilitating the commercialization of university discoveries, thereby converting 'public science into private assets' (Roy, 2017, p. 211). As Kesselheim points out, 'it gave universities authority to retain control of the patent rights arising from government-sponsored research and offer exclusive rights to private firms' (2011: 453). This prompted the conversion of 'publicly funded knowledge into private intangible assets that entered into financial markets and became objects of speculation and shareholder control' (Roy, 2017, p. 211; also see Rai and Eisenberg, 2003, p. 290). Many of the start-ups that venture capitalists fund arose from government-sponsored university research.

Another important regulatory change in the United States released massive new sources of capital available for high-risk start-up ventures. In 1979 the Employee Retirement Income Security Act amended the so-called 'prudent man' rule that had strictly limited the amount that institutional investors, such as pension funds, could allocate to high risk assets including venture capital (Gompers, 1994, p. 2). The new rule allowed them to invest up to 10% of their capital into venture funds; annual pension fund contributions rose from $100-200 in the 1970s to over $4 billion by the late 1980s (Gompers, 1994, p. 2). Venture capital firms multiplied in the Silicon Valley during the microelectronic revolution of the 1970s and 1980s and were attracted to biopharmaceutical companies in the early 1980s (Tyfield, 2008, p. 557; Tulum and Lazonick, 2018, p. 301). These firms helped to launch contemporary tech giants such as Apple and Microsoft, as well as biopharmaceutical firm Genentech.

Digital health has since emerged as a robust area for venture capital activity. The global digital health market was expected to reach $206 billion by 2020 (driven especially by the mobile and wireless health market) (ANDHealth, 2018, p. 14). In just two years, between 2013 and 2015, the number of wearable devices sold in the market tripled to 34.3 million devices (Li, et al., 2017, p. 3). Digital health funding rose from $1.2 billion in 2010 to over $11 billion in 2018 (ANDHealth, 2018, p. 15). In 2019 nearly 1 in 10 venture dollars invested in the US went to digital health; $7.4B was invested in 359 US digital start-ups (rockhealth.com). Investments in medical device companies are about $4 billion annually into 400-600 US companies (Mas and Hsueh, 2017, p. 181). In 2019 the global market for medical devices is estimated at $398 billion, excluding in vitro diagnostic equipment (Beaulieu and Lehoux, 2018, p. 2). The number of digital health products has skyrocketed; in mental health alone by 2017 there were already over 10,000 mental-health related applications available to download (Tourous and Roberts, 2017, p. 437).

Health gains are not the point of capital investment initiatives. As Lehoux et al. point out, 'capital investment is characterized by an "exit orientation", which underscores the notion that the highest returns possible must be generated within the shortest timeframe' (2017a, p. 647). Venture capitalists aim to bring start-ups 'to the most profitable "exit", which may happen through the acquisition of the venture by another company or an initial public offering (IPO) that provides the ability to sell shares to the public' (Lehoux et al., 2017c, p. 513). These exits, or liquidity events, are means to generate returns on investment and reflect the orientation of value extraction (Lehoux et al., 2017a, pp. 647-648). Venture capitalists make their profits 'mainly by capital gain on equity sale' (Gleadle, et al., 2014, p. 72).

Health policy outcomes and innovation policy frameworks operate under different logics, and the supply-side logics (investor dynamics) overshadow the demand-side logics (health policy needs) (Lehoux et al, 2017c, p. 510). Health technology start-ups need to consider the expectations of those 'to whom value is offered (e.g., physicians, nurses, patients, third-party payers); and … capital investors and shareholders for whom value is captured' (Lehoux et al. 2014, p. 1026). Robinson has concluded that 'market concerns increasingly shape the kinds of medical innovations that will be designed and developed for patients' (Robinson, 2018). As a result, the purpose behind the creation of innovative companies "is not to substantially improve health as much as to provide a temporary vehicle for generating returns on investment"' (Lehoux et al., 2018, p. 14).

Regulatory Approval

Regulatory institutions play an essential role in medical innovation. Regulatory approval permits the innovation's release into the marketplace, allowing investors to realize its economic value. Regulatory institutions have not kept pace with medical technology innovation. By prioritizing innovation as an economic driver, the US has relaxed regulatory oversight of many burgeoning medical technologies. In particular, both the US Congress and technology developers have worked to narrow the US Food and Drug Administration's (FDA) oversight role over time. This reduced oversight has led to numerous product recalls and the surprising gatekeeper role of the Apple iTunes and Android Google Play Store for many digital health applications (Tourous and Roberts, 2017, p. 437). The Apple iTunes Store and

Android Google Play have begun to step in to oversee some health apps. 'In September 2016 Apple announced that it would no longer allow certain health applications in its marketplace'; for example, its guidelines include the provision that to be offered through the Apple iTunes Store drug dosage calculators must come from approved health entities or receive FDA approval (Torous and Roberts, 2017, p. 437).

The initial impetus for giving FDA regulatory authority for medical devices was the Dalkon Shield scandal of the early 1970s in which the Intra Uterine Device (IUD) caused grievous medical harm to the many women who used it. In response, the 1976 Medical Devices Amendments foregrounded the 'safety and effectiveness of medical devices intended for human use' (Johnson, 2018: 2). Regulation was hardly immune to the broader economic currents of the 1980s and 1990s. The focus on innovation as a job creator and wealth generator spilled over into discussions of health regulation.

Over time, policy discussions began to shift in the direction of prioritizing innovation as an urgent *public health* goal. As Johnson points out, by the 1990s the notion emerged that '*impeding innovation* was a threat to public health' (emphasis added, Johnson, 2018, p. 9). In 1997 lawmakers prioritized innovation in the Food and Drug Modernization Act; it was the 'first time that the word 'innovation' appeared in device legislation' (Johnson, 2018, p. 9). Flipping the script, the 'statute called for a report on how clinical trial data requirements caused "adverse impact[s] ... on device *innovation* and research" [emphasis added]' (Johnson, 2018, p. 9).

The rhetoric of innovation was often juxtaposed with that of regulation in debates leading up to the 21st Century Cures Act of December 2016. Members of Congress and the medical device sector worried that '"applying a complex regulatory framework could inhibit future growth and innovation in this promising market"' (Nathan et al., 2014, p. 372). Those prioritizing innovation won the debate. Before 2016, the FDA 'was responsible for ensuring that medical devices (including EMRs [electronic medical records] and other health IT) were safe and effective for patients' (Ronquillo and Zuckerman, 2017, p. 537). Under the new law the definition of medical 'device' in the Food, Drug and Cosmetic Act was amended to *exclude* certain software functions intended:

a) For administrative support;
b) For maintaining or encouraging a healthy lifestyle;
c) To serve as electronic patient records;
d) For transferring, storing, converting formats, or displaying clinical laboratory test or other device data and results and certain other related information; and
e) To provide recommendations to health care professionals for clinical decisions, where the user can independently review the basis of the recommendation (FDA, 2017).

President of the Advanced Medical Technology Association (which represents over 300 medical device companies), Scott Whitaker, stated that '"passage of this legislation is a milestone in improving the innovation ecosystem of medical technology and ensuring the availability of new lifesaving, life-enhancing devices and diagnostics for patients"' (PBS News Hour, 2016). Light and colleagues go further and argue that the FDA has been transformed from a regulator into an "industry partner" (2013: 597). Indeed, the FDA earns substantial

revenue from user fees, setting up potential conflicts of interest between the regulators and the regulated.

Hogarth has argued that the culture of Silicon Valley, epicenter of the robust American venture capital industry, is neoliberal, libertarian and anti-regulation (2017, p. 257). Its 'move fast and break things' mantra embraces digital disruption as innovation. Mobile phone app companies exist in some limbo between being software firms and healthcare firms and may be attractive to investors 'hoping for an opportunity to work in the healthcare system without the added costs of regulatory compliance' (Hogarth, 2017, p. 261; also see Moses et al. on devices, 2005, p. 1339). Indeed, a 2006 *Business 2.0* magazine article gave the following advice for those considering entry into the consumer healthcare sector: '"stay clear of services that require you to spend a lot of quality time with the FDA"' (Alseverm, 2006, quoted in Hogarth, 2017, p. 261).

Public health advocates have expressed concerns over patient safety with this relaxing of FDA regulation over digital health. Since the 2010s the number of new digital health interventions on the market has overwhelmed patients and caregivers alike (Mesko et al., 2017, p. 3). Numerous analysts have pointed out the dangers of lax oversight in digital health stemming from mobile phone apps that fail to reflect clinical guidelines and best practices (Moller et al., 2017, p. 8; Torous and Roberts, 2017, p. 437). Digital health interventions can be harmful and may make fraudulent claims, such as those purporting to measure blood alcohol concentration that have no capacity to do so (Murray et al., 2016, p. 848). For example, Torous and Roberts noted one app advising people experiencing a bipolar manic episode to drink hard alcohol to assist with sleeping (2017, p. 437). The 21st Century Cures Act made sure that health applications would be even less stringently regulated (Torous and Roberts, 2017, p. 437).

In the FDA assessment process considerations of cost, health impact, or clinical relevance of a new technology are excluded; 'all medical devices are normatively equal in the eyes of the regulator' (Lehoux et al., 2017a, p. 651; Lehoux et al., 2017c, p. 514). The diagnostics sector faces 'lower regulatory hurdles and has products on the market far faster than therapeutics firms, and their product development process has no equivalent formal regulatory definition of pre-clinical/clinical developmental stages' (Hogarth, 2017, p. 254).

An examination of FDA databases of medical devices recalled between 2011 and 2015 because of software defects found that 627 software devices were subject to recalls (1.4 million units), with 12 of these devices (190,596 units) subject to the highest risk recalls (Ronquillo and Zuckerman, 2017, p. 536). The analysts found that 11 of the 12 highest risk recalls had been approved through the more forgiving 510(k) review process and that the 12th had not been reviewed at all (Ronquillo and Zuckerman, 2017, p. 536). For the 510(k) review the producer just needs to claim that the new device is 'substantially equivalent' to an already-approved device. One of the core problems with the 510(k) review process is that, in a rapidly evolving technological landscape, the concept of 'substantial equivalence' to previously approved devices may not reflect significant and consequential technological differences between the earlier and newer devices. This could jeopardize patient safety.

The largest number of high-risk software recalls included five ventilators and three infusion pumps for hospital use (Ronquillo and Zuckerman, 2017, p. 543). None of these devices had been classified as high risk at the time of regulatory review and had only been required to demonstrate 'substantial equivalence' to other devices on the market that had not been required to prove safety or efficacy (Ronquillo and Zuckerman, 2017, p. 547).

The analysts raise alarm that the 21st Century Cures Act further reduces FDA's regulatory authority and shifts responsibility away from the health technology firms (to prove safety) to health care organizations to report harms after the fact (Ronquillo and Zuckerman, 2017, p. 548). The authors expect the risks of injury from software problems in medical devices to increase. The Public Citizen's Health Research Group and the National Center for Health Research lobbied against the Cures Act and believe that the resulting relaxation of FDA standards will endanger public health (PBS Newshour, 2016).

Implications and ways forward

Examples from the pharmaceutical sector, COVID essentials, digital health and regulation reveal troubling misalignments between 21st century capitalism and public health priorities. It is clear that the economies of health defy simple supply and demand and cost-benefit logic. "Allowing the marketplace to govern issues related to well-being of the public is simply not sufficient" (Tourous and Roberts, 2017, p. 438).

The COVID-19 pandemic throws these misalignments into sharp relief. The indispensable role of public institutions has never been clearer, whether for procuring personal protective equipment, developing testing protocols, pursuing vaccine research or guiding the public response with information and expertise. The private sector, too, has an indispensable role to play, particularly for financing early stage medical innovation. The challenge is how to 'truly assure that we advance technologically, and that we do so in a way that ensures deep and broad public interests are met' (Powles and Hodson, 2017, p. 363). Challenges such as COVID-19 and antimicrobial resistance are two clear and urgent opportunities for pursing public purpose missions. Investment and innovation should be directed at unmet global health needs and products that are accessible and affordable (Mazzucato, 2016: 180).

The fact that the value extractors are profiting to the detriment of innovation suggests the need to realign risk and reward to reflect the social priority of value creation. Medical innovation is cumulative and collective; 'value creation occurs through multiple actors taking risks for the sake of uncertain rewards' (Mazzucato and Roy, 2019, p. 108). Indeed, "national states have been among the risk-takers. They have been major R&D investors especially of the most radical and path-breaking innovations without enjoying their associated profits" (Rikap, 2019: 993). The important role of the 'entreprenurial state' often gets lost in narratives around innovation (Mazzucato, 2013). As Mazzucato and Roy point out, 'the conventional narrative on value assumes a public sector that provides basic goods and then "gets out of the way" of private actors, with innovation an outcome of risk-hungry capitalists' (2019, p. 112). The state can play an essential role in directing, funding and guiding 'public purpose missions in public health – not only to de-risk markets' (Mazzucato and Roy, 2019, p. 101; Torreele, 2016).

To evaluate policy along these lines Walter Johnson advocates a public value mapping, 'to identify and characterize the public values that operate in a policy area' and ask if 'decision-making has successfully delivered on public values that permeate the policy area' (Johnson, 2018, p. 2; see also Mazzucato and Roy, 2019). This approach could be facilitated by more robust and systematic stakeholder engagement. For example, one way to foreground such public purpose in medical innovation would be to stop characterizing healthcare organizations as customers, or 'downstream purchasers, not upstream policy stakeholders' Lehoux et al., 2017a, pp. 644-645). Market logic fails to look at them as partners that should be consulted at every stage. Lehoux and colleagues endorse the World Health Organization's Innovation principles of the 4As: 'Availability, Accessibility, Appropriateness and Affordability' (Lehoux, et. al. 2016b, p. 121). They recommend that healthcare managers, physicians and technology developers foreground and discuss these purposes of responsible health innovation at each stage of the development pathway (Lehoux, et al., 2016b, p. 121).

Beyond early stage consultation, Mazzucato and Roy recommend a deeper structural change, to 'change the rules of the game in shareholder-driven, financial-market-based economies so that companies are accountable to multiple stakeholders, including patients and health systems, rather than only shareholders' (2019, p. 115). Issues of pricing and accessibility of medical innovation need to reflect the substantial investment of taxpayer money into the research and development underpinning this innovation so that 'taxpayers don't pay twice' (Mazzucato, 2016: 180). Firms should be required to offer pricing transparency to reflect the proportion of the R&D that taxpayer dollars funded. There need to be price caps to reflect public inputs. Some have recommended the establishment of prize funds for innovation that meets unmet medical needs as an alternative to the intellectual monopoly capitalism that dominates today's "innovation" landscape. Compulsory licensing of urgently needed medical interventions, such as PPE, should be considered as a way to ramp up production and accelerate access. Executive incentives need to be realigned with firms' productivity, not share price manipulation.

Regulatory reform is urgently needed. Patient safety should be paramount in FDA regulation. The metric of 'substantial equivalence' for the 510(k) review process poses risks in such a rapidly innovating field as medical devices and mHealth. In what way might an outdated technology be seen to be 'substantially equivalent' to a new technology? The FDA product recalls of software-based innovations suggest the need to re-examine some of the regulatory misalignments in the interest of patient safety. The balance between urgent medical needs, innovation and regulation is always complex. The quick FDA approval of second uses of the malaria, lupus and rheumatoid arthritis drug hydroxychloroquine to treat COVID-19 stands as cautionary tale that moving too quickly poses substantial risks. As Nathan suggests, 'robust FDA oversight is not necessarily incompatible with innovation in the mHealth industry. In fact, the industry's long-term potential may depend on it' (Nathan, et al., p. 377). Indeed, Mazzucato and Roy advocate thinking about the government's role as not 'regulating' but rather as 'actively co-shaping markets' (2019, p. 101).

This analysis of the structural economic features of contemporary capitalism has illustrated several areas of public health that are not being well served by current arrangements. This discussion seeks to contribute to what Robinson refers to as an 'economic bioethics'; as

Robinson suggests, "to adequately understand and make sense of global health care contexts that are increasingly modulated according to financial levers, it is imperative to fully understand and analyze issues of finance, markets, and capital as part of larger bioethical agendas and analysis" (Robinson, 2018).

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Acknowledgements
The author wishes to thank Walter Johnson and Sakiko Fukuda-Parr for comments on an earlier draft, as well as the two anonymous peer reviewers who offered constructive feedback on the manuscript. Any errors of commission or omission are mine alone.
Data statement
Data sharing is not applicable to this article as no new data were created or analysed in this study.
Funding statement
This research was supported by the Australian Research Council grant DP180102426.