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Introduction

Multidisciplinary perspectives on the regulation of diagnostic technologies

1. Introduction

There is a burgeoning interdisciplinary literature devoted to the regulation of pharmaceuticals, with contributions by social scientists, historians and legal scholars. In contrast, the regulation of diagnostic tests has received relatively little attention. To illustrate the point using data from this journal: a 2018 search on the term "FDA" found 88 articles on pharmaceuticals and only three on diagnostics. This special issue offers a modest contribution to redressing the imbalance.

We are writing at a time when the global SARS-CoV-2 pandemic has encouraged regulatory agencies to amend regulatory controls to allow more rapid introduction of new diagnostics through the use of emergency authorisation procedures (emergency use authorisation, EUA). EUA regimes have maintained some pre-market controls but the purpose of EUA has a fundamental difference to normal market licensing procedures: there is a concern with issues of supply that are linked to national strategies for use of diagnostic tests in managing the pandemic. This creates new political pressures on the authorisation process that are not normally present in medical device approval. Much remains opaque about this new regulatory approach, but it is indicative that the regulation of diagnostics is a topic worthy of greater scholarly attention. The last year has also seen the US trial of Elizabeth Holmes, former CEO of failed Silicon Valley diagnostics start-up Theranos, an event which garnered further international media coverage for the diagnostics industry's most high-profile scandal and raised critical questions about the governance of diagnostic innovation. These immediate issues aside, there is good reason to believe that this special issue is timely, if not overdue.

Firstly, there is the continued pressure of technological innovation in the post-genomic era, exemplified in recent years by the rapid development of next-generation sequencing, the introduction of non-invasive sampling techniques based on small quantities of circulating target material in blood (whether circulating tumor cells, tumor DNA or fetals cells), and the emerging fields of metabolomics and proteomics. Advocates of personalised/precision medicine continue to promise that post-genomic science will redefine disease taxonomies and transform clinical practice. Given that such heady expectations are unlikely to be realized, there is need for robust regulatory scrutiny of the diagnostic accuracy and clinical effectiveness of new tests, as demonstrated by the limitations of polygenic risk scores revealed in two investigations of the consumer genetics market by the US Government Accountability Office (2006, 2010).

Much of this special issue focuses on genomics, reflecting a general bias in STS scholarship towards emergent science and technology, to the exclusion of both mundane technologies and the social and political arrangements that condition their effects. Yet whether in the promissory space of novel genomic diagnostics or the quotidian world of everyday diagnostic practice, there is growing attention to issues of governance. As quality improvement and patient safety have moved up the agenda for healthcare systems, greater attention is now being paid to diagnostic errors as a cause of clinical harm and wasted expenditure. A recent report from the National Academies of Science (NAS, 2015) suggested that in the USA diagnostic errors are implicated in approximately 10 percent of patient deaths, and 6 to 17 percent of hospital adverse events. Another driver of attention to diagnosis is the growing body of scholarship organized around the concept of overdiagnosis. This is more than just a research agenda. Supported by the British Medical Journal, an international movement has taken institutional form through the annual international "Preventing Overdiagnosis" conference series which has been running since 2013.

Finally, we believe that this special issue is timely because diagnostic innovation is being met not simply with increased regulatory action, but with increasingly multi-faceted (or polycentric) action. In terms of statutory regulation, notable developments are the introduction of new regulations for diagnostic devices in the European Union (EU) in 2017 and in Australia in 2010. Beyond these statutory regulatory frameworks, broader regulatory efforts have been promulgated by two interlinked communities: Health Technology Assessment, which typically operates as an Independent Regulatory Actor (IRAs) (Jordana and Levi-Faur, 2005); and the diffuse network united by the principles of Evidence-Based Medicine (EBM), from which have emerged new standards such as the STARD framework for reporting diagnostic studies (Bossuyt et al., 2003). The last decade has seen new initiatives to advance evidence-based evaluation of diagnostics, such as the diagnostics assessment programme established by the UK's National Institute for Health and Care Excellence, and the EGAPP process supported by the US Centers for Disease Control. There is also some evidence that new molecular diagnostics face heightened scrutiny by health technology assessment (HTA) agencies in the USA compared with more traditional diagnostic tests (Trosman et al., 2011). In the context of low- and middle-income countries, the World Health Organization is playing an increasingly important role in supporting the development of regulatory structures in countries that have none, and in standard setting and test evaluation through its prequalification process (Mori et al., 2011). Such developments exemplify a broader process of regulatory expansion and diffusion in the regimes governing healthcare technology adoption, in particular growing demand for evidence of comparative and cost-effectiveness by HTA agencies, and a greater role for clinical guidelines (Weisz et al., 2007; Timmermans and Berg, 2010).

All of this suggests that there is much scope for greater scholarly attention to the regulation of diagnostics. Why exactly is this shift is

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occurring? What implications does it have for the diagnostics industry, for healthcare providers and patients, and for the organization and effects of regulatory regimes? In this special issue we examine these issues from a range of disciplinary perspectives including political sociology, STS, and social history of medicine.

2. Industry's influence

Any discussion of diagnostics regulation should be informed by some understanding of the structure of the industry. The diagnostics market is essentially bifurcated between the *in vivo* diagnostics firms that produce imaging technologies (X-ray, CT, MRI) and the *in vitro* diagnostics (IVD) firms that produce lab tests (immunochemistry, molecular diagnostics etc.) - though there is a little overlap (firms such as Siemens and Hologic). Both sectors comprise a small number of large multinationals and a long tail of smaller firms; the top ten firms account for 74.1% of global revenues in the IVD sector and 91.5% in the imaging sector (Evaluate, 2018).

Such concentrations of economic power have political effects, not least in the ability to influence regulatory policy. Tracing the impact of corporate power on regulatory policy is largely undeveloped for scholarship on diagnostics, and is thus is an important direction for future research. Processes of transnational harmonisation may be particularly susceptible to corporate capture by multinational firms: for instance, the first draft of the EU IVD Directive was written by the European Diagnostic Manufacturers Association (the European industry trade body) and the framework for the new EU IVD regulation draws heavily on the model developed by the Global Harmonisation Task Force, which was again drafted by industry.

Industry influence over regulatory policy has been a common theme in scholarship on the regulation of pharmaceuticals, conceptualised by Davis and Abraham (2013) as a systematic pattern of "neoliberal corporate bias". That this might be in part an outcome of neoliberal lobbying is suggested by Nik-Kah's historical account of the Chicago School of Economics' campaign against the FDA (2014). Contestation around evidentiary standards is central to the dynamic of neoliberal deregulation in the pharmaceutical sector. Davis and Abraham (2013) describe the period from 1980 onwards as an era of "permissive regulation" and the impact of lowered evidentiary standards and the pressure for faster approval has been exhaustively documented. Why then has the diagnostics sector seen *increased* regulation in the same time period and what does this tell us about the politics of regulation in the neoliberal era?

Leading figures in regulatory studies contend that to characterise the decades after 1980 as a period of neoliberal deregulation is at best oversimplification and that the era can be better characterised as the age of 'regulatory capitalism' (Braithwaite, 2008; Jordana and Levi-Faur, 2005). Tombs (2016) suggests the neoliberal era has witnessed both deregulation and re-regulation but both dynamics are part of a systematic effort "to reconfigure the relationships between state and private capital under the guise of setting the latter free." How does this relate to regulatory expansion in the diagnostics sector? There are undoubted examples of regulation as market construction, such as the EU IVD Directive, drafted by industry to create a single EU market, but as Hogarth and Löblová (this issue) suggest the process of regulatory expansion has a variety of drivers. Their elaboration of the concepts of regulatory niches and fragmented expansion indicate the potential for engagement between STS scholarship and the burgeoning field of regulatory studies. We believe that future work on the regulation of diagnostics offers further scope for such interdisciplinary engagement and we illustrate this by focusing on two themes: the polycentric nature of regulation and the dynamics of standardisation.

3. Polycentric regulation

A key theme in contemporary regulatory theory is the social complexity of the space in which certain regulatory issues are resolved, and which actors have standing within it (Hancher and Moran, 1989). In some of the pioneering work on regulation, economists assumed a simple command-and-control model involving a regulatory body and a regulated industry, but this framework has been challenged by concepts like "de-centred" or "polycentric" regulation (Black, 2008). This new approach addresses the proliferation of regulatory agencies operating with some measure of independence from the state; the different forms regulation takes (self-regulation, regulation by information disclosure etc.), and the array of actors participating in regulatory regimes. Regulated industries, and the regulatory agencies that police them, are situated in broader governance networks encompassing international standard-setting bodies, civil society groups, and the consultancies and law firms that provide technical and legal expertise to regulated industries.

In this special issue, the polycentric character of diagnostic regulation is evident in multiple papers. Holloway and Millller (this issue) explicitly draw on regulatory governance scholarship to adopt the concept of regulatory intermediaries, as they examine the role of independent consultants in supporting diagnostics firms with the constitution and adjudication of standards relevant to decisions about test coverage. As they have explored further in subsequent work (Holloway et al., 2021) there is much that is opaque about how these intermediaries help firms to navigate the regulatory regime governing coverage and reimbursement and the role that the play in shaping regulatory standards. By contrast, Sturdy analyses the very public processes of policy deliberation over how to regulate the growing numbers of genetic tests that became available during the 1990s, and the increasingly diverse range of stakeholders enrolled in the advisory bodies that sought to shape regulatory policy. The deliberations of these bodies exemplify the expansion of regulatory concerns in biomedicine, moving beyond issues of safety and effectiveness to include questions of utility, ethics and public as well as private good (Salter and Jones, 2005). This broader normative agenda has continued to inform deliberation on new waves of genomic innovation such as Non Invasive Prenatal Testing (NIPT), as illustrated by the work of Dupras et al. (2020).

Hogarth and Löblová (this issue) offer a different model of polycentric regulation, using the concept of regulatory niches to analyse the emergence of multiple regulatory structures within the UK's public healthcare system This process of fragmented regulatory expansion was driven in part by transnational networks of experts active in fields such as HTA, EBM and public health genomics. More attention to the progress of diagnostic reform could, they suggest, shed new light on the history of these fields.

The polycentric nature of regulation is exemplified by the parallel development of regimes for market licensing and reimbursement since the 1970s. STS scholarship on pharmaceutical regulation is divided between a large literature on market licensing and an emergent literature on reimbursement regulation focused on Health Technology Assessment, but there has thus far been limited attention to the interactions between these two forms of regulation, even in the relatively well-studied field of pharmaceuticals. Work on diagnostics can lead the way here. Although explicitly eschewing the polycentric regulation framework, Cambrosio et al. (this issue) explore how molecular diagnostics firms entering the US market negotiate a complex regulatory landscape as they seek FDA approval and/or endorsement in clinical guidelines and coverage from both public and private payers. The payers, they argue, loom particularly large in that landscape for manufacturers of genomic cancer tests, not least because of their attention to a broader range of criteria including clinical utility, which FDA tends to avoid. A recent paper by Hogarth and Martin (2021) provides evidence of direct conflict between FDA, HTA experts and professional bodies about the evidence necessary for clinical adoption of pharmacogenetic testing for Warfarin.

Market licensing regulation is even less central to Ilana Löwy's account (this issue) of the international diffusion of Non Invasive Prenatal Testing (NIPT). Although the FDA has yet to approve a single NIPT test, the technology has been widely adopted in the USA where the

regulatory gatekeepers for NIPT have been professional societies and payers. In European countries, adoption has been slower and more limited, but again market licensing has played no role; while in Brazil, the distribution of NIPT solely through weakly regulated private clinics means that regulation has effectively been delegated to the market. The only country where market licensing appears to have had any impact is China, where NIPT has been assimilated to the regulatory arrangements governing genetic testing more generally. Löwy's account illustrates the value of the cross-country comparative method and the need for close attention to the diverse composition of the regulatory space in different socio-technical contexts.

3.1. Standardisation

Löwy's primary explanation for the difference between Europe and the US in NIPT is that European healthcare systems have developed a programmatic approach to screening. As Hogarth and Löblová explain, the transnational diffusion of a programmatic approach to screening reflects the growing influence of WHO's 1968 guidelines developed by Wilson and Jungner (Sturdy et al., 2020). These guidelines establish a detailed framework for the evaluation of screening as a complex public health intervention that goes beyond questions of diagnostic accuracy to encompass intended and unintended clinical outcomes and some measure of programmatic effectiveness. Other evaluation frameworks - both standard HTA and the ACCE (Analytic validity, Clinical validity, Clinical utility, and Ethical, legal and social implications) framework developed for genetic tests – have some of this same breadth. By contrast, market licensing remains, as Sturdy observes, "notably light touch", and largely confined to what, in the terminology of the ACCE framework, would be analytic and clinical validity. Given this disconnect, and the differences between the diverse regulatory niches and evaluation frameworks described by Hogarth and Löblová, it is perhaps unsurprising that diagnostic reformers lament an absence of clear standards:

> "… manufacturers, laboratory professionals, researchers and regulators are equally confused on what studies to do or accept as evidence for the clinical performance and effectiveness of medical tests." (Horvath et al., 2014)

The question of regulatory uncertainty around the evidentiary standards for diagnostics recurs frequently in this special issue, often in relation to the concept of clinical utility. Turrini and Bourgain (this issue) describe how the rapid adoption of genetic susceptibility testing for thrombophilia stalled in the face of growing evidence that their ability to predict illness was limited at best. Several professional bodies revised their clinical guidelines in line with the view that the utility of the tests was insufficient to justify clinical use. Nonetheless, some clinicians continued to use and defend the tests, arguing that evaluation of their clinical utility should take account of benefits to family members as well as to the patients themselves.

Sturdy examines the elaboration of clinical utility as an evaluative metric within the broader ACCE framework for evaluation of genetic tests and locates the origin of the concept in the efforts of clinical geneticists to establish an ethical basis for their medical practice in the shadow of the legacy of eugenics. Sturdy describes the broader diffusion of the concept (also explored by Hogarth and Löblová), noting that wider adoption has been accompanied by shifts in meaning "with clinical and economic effectiveness often taking precedence over evidence of benefit to individual patients or improved patient outcomes" (Sturdy).

Green, Carusi and Hoeyer (this issue) view uncertainties about utility from a somewhat different perspective, situating them in the tension between the precision medicine movement, with its promise to refine and redefine disease categories through the generation of new genomic data, and the need to stabilise disease categories as a basis for clinical practice. In this setting, uncertainty about the clinical utility of candidate diagnostic markers is at once inherent in the dynamics of diagnostic and taxonomic innovation, and at risk of being over-ridden in the interests of advancing the personalised medicine agenda.

At the same time, uncertainty about regulatory criteria and evidential standards creates space for manufacturers and test providers to negotiate and reshape regulation to their own ends. Holloway and Miller (this issue) explore the multiple meanings of clinical utility advanced by regulatory consultants who support industry in navigating the coverage and reimbursement system for diagnostics. These regulatory intermediaries are playing an important role in shaping the practical application of clinical utility in regulatory decision-making, and their growing influence raises "questions about whose interests are represented in the regulation of diagnostic innovation" (p.x).

4. Research and practice - diagnostics as multivalent technology

If there is continued uncertainty regarding the regulatory standards that govern diagnostic tests, this may in part be due to the ambiguous, multivalent character of diagnostic technologies and the complex, diffuse nature of diagnostic innovation. Many scholars will be familiar with the pharmaceutical innovation process, in which a single firm is the primary actor responsible for generating clinical data to support an application for regulatory approval. Diagnostic innovation is generally a more socially complex process, which has occurred through diffuse networks of actors operating at the interface of the clinic and the laboratory in what Hopkins (2006) has termed a "hidden innovation system". It is hidden because it has attracted little attention from those engaged with innovation policy, but also because it has generally escaped the attention of formal oversight mechanisms. However, it is not a regulation-free space; instead diverse groups of actors collaborate on processes of technical standardisation to enable the use of new biomarkers as both research tools and clinical diagnostics. It is this collective knowledge production process that Cambrosio et al. (2006) have described as a new form of "regulatory objectivity" that underpins modern biomedicine's realignment of the normal and the pathological. Efforts to implement formal regulatory regimes from outside biomedicine intersect with new developments that bolster the hidden innovation system. The enthusiasm for genomics has provided enhanced funding for translational science programmes that encourage "novel forms of clinical research designed to extend genomics into the clinic" (Kohli-Laven et al., 2011).

By contrast, Green, Carusi and Hoeyer (this issue) show how the multivalency of new diagnostic technologies can also undermine the establishment of regulatory objectivity within clinical innovation. By analysing how diagnostic and other clinical data proliferate in the effort to delineate new, data-led diagnostic categories, they argue that the pursuit of personalised medicine results not only in a lowering of the evidentiary threshold for the introduction of new medical technologies, but in a "reversal of the relationship between evidence and treatment" that has previously underpinned the conduct of clinical research. At issue is not just the regulation of diagnostic technologies; diagnostic classification, they remind us, itself plays a vital regulatory role within healthcare, from sanctioning the allocation of patients to treatment pathways, to determining the flow of funds within institutions and healthcare systems.

The use of biomarkers in drug development is illustrative of the multivalent capacity of diagnostic technologies to generate both experimental data and clinical information. Turrini and Bourgain argue that diagnostics are deployed "at the intersection of clinical research and contingencies of medical practice" (p.x), and many leading diagnostics firms cater to both the life sciences research market and the clinical laboratory market. Products may be labelled as "Research Use Only" in the USA but sold as clinical tools in Europe, and used across research and clinical settings in both jurisdictions. Is this a supply-side issue of firms practising regulatory arbitrage, or a demand-side manifestation of pathologists' enthusiasm for engaging in off-label use? The multivalent capacities of diagnostic technologies may confound efforts to demarcate a clear boundary between research and practice, but the choices that actors make about how to exploit those technological capacities, and the

latitude for action those actors enjoy to make such choices, can only be understood through analysis of the interests of those actors and the capacity of the regulatory regime. When the two largest markets in the global system either operate a system of self-certification for most products (the EU), or permit firms to completely bypass the market licensing regime (the USA), then regulatory power is greatly attenuated.

5. Conclusion

What other directions might this new field of research take? We make three suggestions. Firstly, we might pay greater attention to the firm as an object of regulatory attention. STS scholarship on regulation focuses overwhelmingly on the regulation of scientific practice and technological artefacts, but there is scope for other approaches. To return to the Theranos scandal, the issues at stake were not simply whether the technology worked, or whether the clinical laboratory was engaging in negligent practices, but that the firm's senior executives were misleading investors. Theranos did not only fall foul of the FDA; it fell foul of the Federal Trade Commission. The broader array of regulatory regimes governing the corporate behaviour of diagnostics and other medical firms may provide new opportunities for STS scholars to investigate the nature and extent of corporate power in the contemporary era. This more expansive approach might intersect with established STS research interests, for instance those interested in the drivers of technology adoption might usefully investigate the use of financial inducements by clinical laboratories (in the USA there has been a spate of federal prosecutions of clinical laboratories offering, and physicians receiving, financial kickbacks for lab tests).

Our second suggestion is more attention to the practice of regulatory decision-making across the full product lifecycle. One consequence of the STS bias to emergent technologies is a tendency to focus more on legislative processes and standard-setting than on the implementation and enforcement of regulation (Abraham and Davis, 2007). Following the trajectory of technologies through multiple regulatory gateways – market licensing, clinical guidelines, coverage/HTA – is a promising approach and one that would benefit from the kind of cross-country approach adopted by Lowy in this issue. As Hogarth and Löblová suggest, one useful approach in cross-comparison would be to look at the intersection of the different evaluative frameworks for diagnostics that have diffused across the globe in recent decades.

Finally, we urge a greater attention to mundane technologies. The recent call for a turn away from innovation and towards maintenance (Russell and Vinsel, 2016) suggests an important direction for future scholarship on the regulation of diagnostics. The cutting-edge of personalised medicine will continue to attract attention, but future research must follow the example of scholars like Faulkner (2009) and Clarke and Casper (1996) in investigating the governance of mundane, but pervasive diagnostic technologies such as glucose meters and pap smears.

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