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Patient engagement in drug development: configuring a new resource for generating innovation

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ABSTRACT

This paper focuses on the recent interest in patient engagement (PE) in drug development, expressed in the growing number of calls for engagement, novel organizations dedicated to changing the culture of drug development, and guidelines for directing and evaluating PE. By reviewing materials produced by actors in the field and analyzing publications reporting on PE initiatives, I map sites of action where PE is being conceived and practiced, delineate how PE is being shaped, and analyze relationships emerging within and around the collectives involved. Pharmaceutical industry players actively mold the landscape of PE in drug development through creating tools and frameworks for PE. These instruments for guiding the implementation of PE are disseminated via training and dedicated events, concurrently disseminating a particular configuration of PE. PE emerges as an attempt to open new avenues for increasing productivity amidst concerns about the future of drug innovation, while PE practices fit smoothly into the arrangements for producing and distributing pharmaceutical knowledge largely shaped by the industry. The ongoing participatory turn in drug development is taking place without shifting the established concentration of epistemic power among commercial entities.

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Introduction

In 2015, a manifesto calling to partner with patients in drug development was published (Hoos et al.). In the manifesto, representatives from the pharmaceutical industry and several not-for-profit organizations characterized existing patient engagement as 'fragmentary at best' and urged that patients be systematically engaged in all stages of the drug development process. This publication was one of the first in a wave of pleas, position papers, and roadmaps calling for patients to play a more central role in the creation of new pharmaceuticals. The overt aspiration articulated by the commentators is to move away from limiting patients to simply choosing whether to participate in clinical trials or seeking their contribution at the launch stage, when only promotion strategies are left to be considered.

Advocates of patient engagement in drug development have stressed the urgent need for change by comparing the pharmaceutical domain with the health-care domain. In health care, the last two decades have witnessed the proliferation of practices to facilitate the participation of users, both actual and potential, at various levels, from direct care to organizational governance and policy

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making (Carman et al., 2013). Against this background, drug development – carried out predominantly by pharmaceutical companies – has appeared to lag behind by persisting in its non-participatory mode of operation.

For a number of years, the pharmaceutical industry expressed little interest in the participatory turn taking firm root in health care. More recently, however, multinational pharmaceutical companies and their allied actors have begun to acknowledge that 'engaging patients in the drug development process is not yet commonplace for most pharmaceutical companies' (Lowe et al., 2016, p. 870) and to identify this lack of engagement as a problem. One way of interpreting this move might be to view it as an expansion of the trend toward greater participation from the public sector in the corporate world. At the same time, expectations articulated with regard to patient engagement in drug development suggest a specific understanding of patients' contribution and its value. Although not always readily apparent amidst the pledges to give patients a voice, there is an aspiration to reinvigorate innovation visible in claims that drug development be made 'faster, more efficient, and more productive through systematic patient involvement' (Hoos et al., 2015, p. 935).

In this article, I focus on this recent interest in patient engagement in drug development. This interest is expressed now not only in calls for engagement but also in the growing number of empirical reports and analyses, in the novel organizations dedicated to changing the culture of drug development, and in the guidelines and metrics offered to direct and evaluate patient engagement (Cavaller-Bellaubi et al., 2021; Feldman et al., 2021; Stergiopoulos et al., 2019). I discuss how the patient contribution to drug development is being configured as a resource for generating innovation, firstly, product innovation but also process innovation aimed at smoothing the process of development itself, including clinical trials, its most costly component. Hereafter, for the sake of clarity, I employ the term patient engagement (PE) for drug development because it is the most common way of denoting activities aimed at enhancing collaboration between patients and development teams.

Patient knowledge and distribution of epistemic power in the pharmaceutical domain

Critical social science scholarship has highlighted how efforts to promote pharmaceutical consumption have defined relationships between the pharmaceutical industry and society. Studies have explored industry practices of curating publications in medical journals to support marketing of specific products (Sismondo, 2009) and of establishing relations with physicians to shape their prescription behavior (Fugh-Berman & Ahari, 2007). Research has also shown how demand for drugs is fueled by identifying more and more conditions as requiring pharmaceutical intervention, switching from treating diseases to treating risks, and lowering thresholds of risks deemed to be in need of treatment (Dumit, 2012; Fishman, 2004; Fox & Ward, 2008). Importantly, industry promotion efforts are inextricably tied to knowledge production and circulation: from clinical trials that are unlikely to ask when a patient should stop taking a drug to publication planners who carefully construct and place papers reporting on trial results to key opinion leaders, who then educate physicians about drugs based on published data (Sismondo, 2018). In the process, conditions are established for maximizing diagnoses, prescriptions, and purchases. With pharmaceutical knowledge being central to expanding markets, the power to define how this knowledge is produced and channeled has been disproportionally concentrated among pharmaceutical industry players. Sismondo (2018) warned that 'because those companies have concentrated influence and narrow interests, consumers and others should be concerned about how epistemic power is distributed'.

Until recently, the role of patients in this entanglement of medical experiments, metrics and facts, conferences, journals, and promotional materials has been that of a consumer of both pharmaceuticals and the knowledge created to substantiate the necessity of pharmaceutical consumption. Patients' participation in pharmaceutical knowledge production has been limited to providing their

bodies for experimentation. Subsequent dissemination of this knowledge has been directed at molding their preferences (Wilkes et al., 2000). However, the emerging turn toward PE in drug development denotes a reconfiguration of the value of patients' own knowledge and could change the role accorded to them.

To locate this reconfiguration within critical theories of PE, I briefly outline conceptions of patient and public engagement in health care, an adjacent field with a much longer tradition of user participation (Ocloo & Matthews, 2016; Oliver et al., 2008). Patient and public engagement practices in health care are grounded in what can be roughly considered as two distinct ideologies. One ideology is democratization (Thompson, 2007), which emphasizes fulfilling the rights inherent in citizenship and responding to the current delegitimation of wider political processes (Martin, 2008). Engagement in health care is conceived of as part of the response to citizen distrust and alienation, designed to increase accountability and share decision-making, thus improving care quality and public health.

The other ideology is economically motivated consumerism, which emphasizes individual choice in the marketplace (Dent & Pahor, 2015). Consumerist participatory initiatives in health care anticipate that enhanced choice will lead to greater patient satisfaction and empowerment. Improvements in the quality of health care are anticipated as well since, when presented with multiple choices, consumers are expected to 'vote with their feet' and create competition, which in turn drives health-care quality up. While in practice the initiatives rooted in these approaches can coexist in various uneasy combinations (Latimer et al., 2017), the ideologies of democratization and consumerism form two distinguishable axes along which patient and public engagement in health care can be positioned (Fredriksson, 2013).

In addition to democratization and enhancing consumer choice, Martin (2008) distinguished yet another rationale for patient and public engagement in health care: the technocratically beneficial input that emerges from the knowledge and experience of lay people. This technocratic rationale does not rely on representative participation to gauge collective perspectives as envisioned by democratic rationale, nor does it focus on choice as the central involvement mechanism posited by consumerist rationale. Rather, it emphasizes experiential representation based on shared experiences. Authenticity of the representation, then, is not about statistically reproducing traits of the general population but about assessing and reflecting upon the commonality of situations and needs (Frankish et al., 2002).

PE in drug development cannot be neatly mapped onto this system of coordinates. However, as shown in this article, it builds on the idea of the centrality of experiential knowledge and reshapes it to fit the commercialized environment. The initial attempts by the industry to tap into patients' experiential knowledge have not necessarily involved radical rethinking of patients' role. For example, Lupton (2014) studied social media platforms aimed at eliciting patients' accounts of illness and therapies. Platforms such as PatientsLikeMe invite patients and caregivers to exchange their experiences and opinions and to meet others with similar conditions, thus producing and sharing data fed into large aggregated data archives. Users must agree to their data being gathered and transferred to third parties, but these agreements are rarely explicit. Where such a possibility is explicitly specified, data gathering is usually described in terms of patients being better citizens who manage their own health by communicating with others and contributing to the greater good by sharing their data, which then may be used for developing better medical treatments. However, despite this discourse of democratic sharing of information for everyone's benefit, Lupton discerned a commercialization of patients' written accounts that are then sold to partners, such as pharmaceutical companies, and used for selling advertisements, goods, and services to platform users. Patients here are configured as sources of raw data that are collected surreptitiously and subsequently commercialized.

Similarly to Lupton, Cooper (2012) focused on social media platforms but posited that patients active on these platforms are not merely sources of data; they are an unwaged skilled labor market. What makes this labor skilled is the expertise of patients in the 'minutiae of consumer pharmacology'

(Cooper, 2012) and willingness to self-experiment. The value of patients' expertise, according to Cooper, should be understood against the vector of the pharmaceutical industry's efforts to reform the dominant mode of biomedical knowledge production. Centered around hypothesis testing via randomized controlled trials, this mode precludes generation of the unexpected. To facilitate the generation of surprises that can lead to further innovation, the pharmaceutical industry is moving experimentation away from the confines of the traditional laboratory and to the distributed patient laboratory. Platforms such as PatientsLikeMe serve as access points to this patient laboratory and make it possible to solicit non-standard practices of drug consumption, thereby tapping into semi-regulated spaces of public experiment. Whilst this switch to engaging patients in the identification of the unexpected is not antithetical to democratization, it can be viewed more productively, Cooper argued, as an alternative business model that demands patient participation in the coproduction of commercializable scientific knowledge. By engaging patients, industry may find a way to generate the unexpected in biomedical research and, thus, reinvigorate its ability to innovate.

In what follows I trace the emergence of PE in drug development as further evolution of the model identified by Cooper. To be clear, the shaping of PE in drug development by commercial interests does not necessarily preclude the emergence of pharmaceuticals more attuned to patients' experiences and needs. Rather, I am interested in how the ongoing participatory turn in drug development relates to the hitherto unequal distribution of epistemic power in the pharmaceutical domain.

Methods

This research aimed to map sites of action where PE is being conceived and practiced, delineate how PE is being shaped, and analyze relationships emerging within and around the collectives involved. To accomplish this, the study relied on literature and document analysis conducted in four stages.

The first stage involved a systematic search of academic journals for articles on patient engagement, involvement, and participation in drug development. An electronic search strategy was developed by a trained search strategist and adapted for the following databases: EMBASE, PubMed, and Web of Science (see Additional File 1 for summary of search strategies). The search focused on the 'patient' as a 'research partner' engaged in shaping drug research and development. A background literature search indicated that the terms 'consumer' or 'public' participation, while prominent in many fields, were rarely used in the field of drug development.

The second stage involved sorting and selecting retained articles. After initial screening, remaining articles were divided into non-empirical and empirical articles. The non-empirical group included calls for action, position papers, roadmaps, and tools for PE in drug development. The empirical group included those articles that reported initiatives to engage adult patients in any form of activities during any of the stages of drug research and development. All original publications were eligible to be included in the empirical group if the reported initiatives implied some degree of an impact on drug development practice and provided sufficient detail on the process of PE.

The third stage involved analyzing non-empirical articles and other documents identified through these articles. My approach to analyzing them was inspired by Asdal and Reinertsen's (2022) method. These authors emphasized that a document entails action, and an analysis can discern what it does. Documents, which in this study included calls for action, position papers, roadmaps, tools for PE, website pages, and event materials, are parts of their environments and fields of practice in which they are produced. Simultaneously, they can shape these very same practices and intervene in their environments. My analysis, thus, focuses on what the collected documents do and enable. To discern this, Asdal and Reinertsen offered a number of methodological moves, three of which – sites, tools, and issues – are central to the topic at hand. That is, I interrogated 1) which sites these documents are part of and how they contribute to producing these sites, 2) how they establish particular issues as worthy of attention, and 3) what kinds of issues emerge as a result and how they are transformed and solidified.

The fourth stage involved analysis of retained empirical articles (69 in total). A data extraction form was developed for their systematic examination (see Additional File 2: Data Extraction Spreadsheet). Information extracted for each article included, among other characteristics, who was engaged, how PE was initiated, PE methods, depth of engagement (at which stage of drug development PE was initiated), and intensity of engagement (how much influence patients actually had). Depth and intensity of engagement were judged based on the Framework for Analyzing Patient Engagement in Drug Development (Zvonareva et al., 2022). Further included articles were grouped according to depth and intensity of PE activities reported. Finally, methods and aims of PE activities within each group were examined, and the identified characteristics within and between the groups were compared. This produced a narrative synthesis of the data, which was critically discussed with other members of research team.

Configuring PE in drug development: emerging 'ecosystem' and practices

Shaping the landscape of PE in drug development

Contacts between pharmaceutical companies and patients, beyond the latter's involvement in pharmaceutical clinical trials, have long been surrounded by controversy. In particular, concerns have been voiced about industry sponsorship of patient organizations (Mulinari et al., 2020). Critics have stressed that industry practices, such as funding patient organizations in commercially high-profile areas and establishing such organizations where there are none, could lead patient organizations to (perhaps inadvertently) further their sponsors' interests (Ozieranski et al., 2019). Somewhat broader, there is a fear that close ties between patient organizations and pharmaceutical companies might 'nudge' the entire sector toward specific emphases and selectively enhance those patient voices that align with industry priorities (Fabbri et al., 2020).

The present turn toward PE in drug development appears to circumvent these concerns altogether. Instead of finances being transferred from the industry to patient organizations, relations are reshaped to involve the transfer of knowledge from patients to drug developers. Drug developers, primarily the industry, are in turn to compensate patients for their input calculated according to, for instance, fair market value (National Health Council, n.d.). The outlines of these new industry – patient relations have been visible since the mid-2010s, when there was a notable increase in published accounts of PE in drug development (Zvonareva et al., 2022). But signs of change could be seen as early as 2012, when two large-scale attempts to redefine patients' role were initiated. The first was the Patient Focused Drug Development (PFDD), launched by the U.S. Food and Drug Administration (FDA), to 'obtain the patient perspective on specific diseases and their currently available treatments' (Chalasani et al., 2018). The second was the European Patients' Academy on Therapeutic Innovation (EUPATI) that came into existence that same year in the European Union. The EUPATI was conceived and funded by the Innovative Medicines Initiative (IMI)—a public – private partnership between the European Commission and the European Federation of Pharmaceutical Industries and Associations (EFPIA). It is focused on increasing patients' capacity to 'be effective advocates and advisors in medicines research and development' (EUPATI, n.d.) through training and education.

Subsequent shaping of the PE landscape in drug development suggests the active involvement of industry actors. First, novel initiatives have emerged to create PE tools and frameworks. One example of such an initiative is the Patients Active in Research and Dialogues for an Improved Generation of Medicines (PARADIGM), a project financed by the IMI and supported in kind by the EFPIA from 2018 to 2020. PARADIGM produced the PE Toolbox, which is aimed at making PE 'easier for all', and metrics, which are designed to evaluate 'return on engagement', including the impact of PE in such areas as research relevance, study quality and efficiency, empowerment, and product uptake (Vat & Schuitmaker-Warnaar, 2021). The project also had a larger ambition of supporting 'systematic change in all stakeholder organisations involved in

medicines development across Europe', which it realized by producing a roadmap to 'achieve system-wide sustained PE' and promoting the project's developed tools (Cavaller-Bellaubi et al., 2021). PARADIGM emphasized uniformity and scalability of not only how PE is conducted but also how it is conceived and valued, which appears to have been appreciated by the project's audiences as well. Indeed, a statement by the secretary-general of the European Patients' Forum indicated:

> PARADIGM will help to change the landscape of meaningful patient engagement in the life-cycle of medicines – both in practical terms, but also crucially in terms of mindset and commitment. (PARADIGM, n.d.)

The same emphasis is noticeable in the work of the Patient Focused Medicines Development (PFMD), an initiative established in 2015. It involves companies, patient organizations, and other members such as regulators; it is funded by for-profit members and seeks to streamline PE by sharing a coherent 'reference framework adaptable across stakeholders and the lifecycle medicine' (Patient Focused Medicines Development, n.d.-a). The framework the PFMD promotes is meant to substitute what it presents as disparate and, hence, ineffective efforts, with uniform 'impactful and consistent PE' (Feldman et al., 2021). The initiative seeks to make its vision more tangible through Synapse, a digital PE network set up to map information on PE activities, people, organizations, resources, and events. The Synapse website aptly stresses that through this very act of mapping, the network 'is bringing to life its whole related ecosystem', animated by the aspiration to achieve 'more effective action bringing initially disconnected, uninformed, isolated or duplicative activities within a structured and actionable digital network for stronger impact' (Patient Focused Medicines Development, n.d.-b).

Second, these new initiatives that are striving to standardize PE in drug development have populated the emerging landscape with events and training. One such ongoing series of events, entitled the Patient Engagement Open Forum (PEOF), went live in 2018. It is sponsored by pharmaceutical companies; organized by the PFMD, EUPATI, and European Patients Forum; and in 2020, was reported to have attracted more than 1,500 registered participants per event (Patient Engagement Open Forum, n.d.-a). Events such as the PEOF simultaneously serve as dissemination platforms and knowledge solicitation sites, a dual orientation that can be seen in the objectives of a 2019 PEOF session on creating future PE tools:

> The participants will bring their collective expertise to influence and inform the construction of new tools which will shape the future of patient engagement … By the end of the session, they will be aware of recently developed materials, and collaboratively have arrived at the direction for future co-creation of the next generation of patient engagement tools. They will also have increased their understanding of priorities and material needed for patient engagement. (Patient Engagement Open Forum, n.d.-b).

Attendees thus, were to learn about new materials and absorb information about what should be emphasized and prepared for PE while at the same time sharing their own ideas about appropriateness, focus, and the format of future tools. More generally, the PEOF is explicitly geared toward shaping the PE landscape or, using its own terminology, 'ecosystem', by showcasing initiatives that serve as examples of proper PE in drug development. Hence, it puts forward individuals and organizations as actively involved in furthering PE and solidifies ties between them and newcomers so as to create a like-minded community that is 'working together to make patient engagement the norm through tools, recommendations, good practices, framework and capacity building' (Patient Engagement Open Forum, n.d.-c).

Pharmaceutical industry players thus actively mold the landscape of PE in drug development through creating tools and frameworks for PE. These standardized instruments for guiding the implementation of PE in practice are disseminated via training and dedicated events, concurrently disseminating a particular conception of PE and facilitating emergence of communities of practice around this conception.

Conceiving and practicing PE in drug development

It is perhaps unsurprising that the aspiration of operational efficiency, characteristic of businesses, also characterize the most visible initiatives in the field given that the pharmaceutical industry has taken a central role in defining and promoting PE in drug development. The focus has been on the development of standardized tools that could facilitate easier integration of PE into company operations, potentially decreasing the costs of adoption. Standardization also promises scalability to prevent duplication and unnecessary variation among PE practices, which is seen as a waste of resources. Interest in metrics that can evaluate return on engagement is directed at ensuring that the input into adopting and practicing PE is balanced by the output gained.

What kind of output is expected? The move to embrace PE in drug development can be juxtaposed with the state of the global pharmaceutical industry. Some analysts have called this state a crisis, signs of which include few new drugs with therapeutic advantages over existing ones (Light & Lexchin, 2012) and increased spending on research and development without corresponding increases in innovation (Pammolli et al., 2011). Others prefer to speak of declining productivity, which from the industry perspective means being unable 'to develop sufficient numbers of new drugs to replace existing treatments coming off patent' (Sams-Dodd, 2013, p. 211) and, consequently, being unable to maintain a customary level of profitability. When speaking of reasons for this situation, drug development enterprise participants often cite the problems inherent in the 'paternalistic 50±year-old product-centric [R&D] paradigm that is now plagued with delays, inefficiencies, and high failure rates' (Stergiopoulos et al., 2019). PE is expected to produce 'a new philosophy and new strategies and tactics' to address these problems and make innovation in pharmaceuticals more productive' (Getz, 2019).

Sometimes the connection between PE and more productive drug development is cast in terms of companies' access to markets. An example can be seen in the description of a workshop held as a part of PEOF-2019, entitled 'How to engage patients in early development and preclinical research phases of medicines development'. The description begins by listing the benefits of PE at the clinical development stage:

> [t]his collaboration generates more consistent trials, improves trial recruitment rates, and speeds up the medicine development process which can lead to faster filings towards regulatory bodies and higher rates of approvals (a program co-created with patients has a 20% chance higher of obtaining Marketing Authorization). (Patient Engagement Open Forum, n.d.-d).

However, more often, the connection between PE and more productive drug development is made via creation of better treatments that speak to the interests of both the industry and patients. A recent qualitative study by Hansen et al. (2020) found that the creation of better treatment solutions is expected by the industry, patient organizations, and regulators alike as the main outcome of PE. Specifically for the industry, such better solutions are expected to protect from business failure, as the authors summarized: 'The wish to innovate and evolve with the need of patients in mind and to avoid business failure is a key driver for the pharmaceutical industry' (Hansen et al., 2020).

With a host of new actors and PE mainstreaming efforts on the rise, descriptions have also been published of how PE in drug development is conducted in practice. Some reported PE initiatives are geared toward optimizing clinical development, specifically clinical trials. The clinical trial stage has long been associated with high costs and delays, largely due to recruitment problems and the attrition that occurs when trial participants leave and provide no data on their outcomes. PE at the clinical trial stage is geared toward addressing these issues. PE practices range from surveying patients to testing new recruitment and retention solutions with them, and collaboratively developing such tools as outcome measures and eligibility criteria to ensure clinical trials are conducted efficiently. Several identified initiatives, originating mostly from public hospitals and universities, have asked trial participants to share their motives, decision-making processes, experiences, and/or expectations with regard to trial participation. The intention is to use this input to improve trial

information materials and informed consent processes as well as to enhance enrollment more generally (Dellson et al., 2018; Godskesen et al., 2016). Other initiatives have gone down the route of soliciting patient input by using different methods to invite them into a trial and then determining which methods were more effective at trial enrollment (Sygna et al., 2015). Others still have involved the development of specific tools to improve trial preparedness, understood as the ready availability of resources, such as accepted data collection tools and measurement techniques to speedily initiate and smoothly carry out trials in particular disease areas. For example, the initiative described by LoRusso et al. (2019) aimed at hastening drug development for facioscapulohumeral muscular dystrophy by developing standardized outcome measures, defining minimal clinically important changes, and establishing patient characteristics relevant for refining eligibility criteria. The development process, led by academics, proceeded with patients participating by sharing their perspectives on the outcomes meaningful to them, helping refine areas of functional importance, and determining the adequacy of the functional measures.

Other reported PE initiatives have focused on product development at earlier stages, when patient input can have implications beyond the mode of testing, such as on the product being developed itself. It is notable that identified PE initiatives initiated at earlier stages of drug development tend to be carried out by the industry, while non-industry actors appear to be more active in the later stages. For example, industry authors have described a standardized process of generating patient-based evidence. It was developed in an effort to implement the 'patient engagement roadmap in a hands-on patient-centric drug development process' (Cook et al., 2019, p. 2). In this process, after the initial desk review, a social media listening (SML) analysis was conducted, which was then followed by corroboration and expansion of what had been learned by interacting with patients or caregivers using online bulletin boards (OBBs). The SML involved using specific keywords related to a health condition of interest and searching for these on social media platforms. Posts identified as containing these words were extracted, filtered, indexed, and then analyzed to 'derive patient-specific qualitative and quantitative insights' (Cook et al., 2019, p. 3). The OBBs were run for several days or weeks. They were moderated, asynchronous (meaning that patients could log in at different times), closed, forum-like platforms where patients could anonymously answer predefined questions and engage in discussions.

In another publication, a related group of authors elaborated that during the SML, the following questions and objectives were pertinent: 'Observe patient conversations; What affects, what motivates the patients? What are the questions, pains, experiences, concerns? How do they communicate about their disease?' During the OBB, drug developers were instructed to ask 'specific questions; Explore the disease experience; Understand the priorities; Detect potentially hidden aspects; [and] Further understand the communication' (Patalano et al., 2020). Collected insights were further made actionable by conducting quantitative patient preference studies.

By examining the questions and objectives proposed for different stages of gathering patient-based evidence within the described PE initiatives, we can see that it is innovation-generating insights that are being sought, the unexpected that would otherwise not be known or noticeable to drug developers. For example, implementing one of the PE initiatives described above, a company learned that urinary incontinence due to cough was a major problem for patients with COPD, who, nonetheless, were uncomfortable talking about it even amongst themselves on dedicated online forums (Patalano et al., 2020). The problem turned out to be a complete surprise for the drug development team. These initiatives highlight how PE can allow drug developers to learn about relevant outcomes, unanticipated effects, and hidden priorities, obtaining leads for innovation.

Discussion

Presently, the industry appears to be the most active in defining the contours and aims of PE in drug development. This dominant role could be supported by an alignment of interests across actor groups, including regulators. As indicated by Hansen et al. (2020), industry investment in promoting

and standardizing PE can result in a set of practices that regulators may rely on to judge the relevance of applications for market authorization. This is how one regulator interviewed by Hansen et al. (2020) described the connection between PE and the drug approval process: 'If you can demonstrate that you have made an analysis showing that patients are interested in this and this … you will also have a better case, meaning that it will help you achieve the approval faster' (p. 580). Such connection would, in turn, be of interest to the pharmaceutical industry eager to see expedited drug approval process.

PE in drug development is being configured in such a way as to tap into the resource of patient knowledge through patients making this knowledge accessible and actionable to development teams. Furthermore, patient knowledge is viewed as the source of the unexpected, in line with what appears to be a larger trend in biomedical research. Previous social science research has identified a move in contemporary oncology clinical trials from being testing machines for drug safety and efficacy to also being clinical experimental systems that allow novel and unanticipated insights to be produced (Nelson et al., 2014). Nelson et al. conducted their research on publicly and charity-funded clinical trials and argued in conclusion that the trend toward more experimental styles of research is not limited to oncology alone, suggesting that the interest in the generation of the unexpected can be detected in other biomedical fields. The shaping of PE in drug development, as discussed in this article, attests to the desire to open the industry-dominated processes of drug development to the unexpected as well.

PE as a way to generate the unexpected in drug development assumes a particular role for patients. Attention is directed at accessing, gathering, and involving patients' struggles, concerns, observations, solutions, hidden choices considered and made, and ways to evaluate their health and the effects of potential interventions. Patients have become the owners of valuable knowledge that needs to be employed to reinvigorate pharmaceutical innovation. This new role of patients and the value attached to their knowledge contrast with the familiar role of consumers assumed by industry promotion practices, as consumers are expected to receive and act on the knowledge produced by the industry.

At the same time, the industry focuses the participatory turn on the role of patients in closing the knowledge gap between themselves and drug developers rather than on increasing the (democratic) decision-making power of patients. Current PE practices rest on the idea that it is sufficient to focus on harvesting experiential knowledge in the absence of increases in patient participation in core decision making. At this moment, it is unclear what kinds of results are generated by these practices. Yet, we can expect that the solid focus on knowledge only may endanger the possibilities for long-term collaboration that would be important for PE to bear fruit. The emergence of PE in drug development is certainly shifting the established ideals and practices of how pharmaceutical knowledge is produced, but its sustainability and outcomes may well depend on whether attention is paid to the power-sharing arrangements along with this newfound appreciation of patient knowledge.

Still, perhaps even more importantly, as the drug development field is undergoing a participatory turn, the long-established distribution of epistemic power is being preserved. PE practices fit smoothly into the arrangements for creating and distributing pharmaceutical knowledge largely shaped and maintained by the industry. These arrangements are not for producing unjustified or false claims. Rather, they are about establishing terms for thinking about health and illness, defining our understanding of certain diseases and treatments, and making particular knowledge salient, all of which facilitate the creation and expansion of markets. With industry at the forefront of defining how PE is conceived and practiced in drug development, PE becomes a mechanism for plugging patient knowledge into dominant pharmaceutical knowledge-production arrangements. It is possible that under these circumstances, patients' interest in better treatments and the industry's interest in profit maximization coincide. But this is not guaranteed since patients are engaged on the conditions that preserve the concentration of epistemic power among commercial entities and their narrow interests.

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