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The Changing Landscape of Health Innovation Networks to Foster Research and Development

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Abstract

In recent decades, major changes have occurred in the landscape within which R&D for health takes place. Of particular importance has been a fundamental shift in the character of the pharmaceutical industry, involving both a concentration through mergers and acquisitions and a dis-integration into horizontal, separate activities, opening new spaces for the entry of academic R&D centres, early stage biopharmaceutical companies and contract research organizations. There have also been major shifts in the nature and purpose of R&D for health and in the range of health challenges for which health innovation is needed. In response, health innovation networks have generated new forms of collaborations with diverse goals, methods of working and degrees of formalization, openness and sources and levels of funding.

The chemical sciences have played a central role in R&D for health, including in many areas of prevention, diagnosis and treatment. There are major current and emerging global threats to health that require strong contributions from chemistry. However, while chemistry's ***potential*** to go on making contributions is huge: its ***actual capacity*** is constrained by a number of current systemic factors and threats, so that its ***delivery*** is likely to be substantially less than optimal. The most serious threats involve three systemic fragmentations: (1) in the science discipline; (2) in the industrial sector; and (3) in the regulatory sector.

The diversity and scale of problems and challenges is such that piecemeal fixes are insufficient – a comprehensive overall approach is required, that employs 'systems thinking' and engages widescale, systemic reform to achieve ambitious goals in 'chemistry for health'. In responding to each of the three systemic fragmentations discussed, an expansion in the number and range of health innovation networks (including diverse initiatives, alliances and partnerships) is proposed as an essential contribution to overcoming the barriers to progress.

1	I would like to thank the organizers for inviting me to participate in this conference and requesting that I give a talk on the changing landscape of health innovation networks to foster research and development. This is a very large subject – and I decided at the outset to make my task seem even bigger by changing the scope from 'networks' to 'networks and other collaborations'.
2	The reason is the lack of clarity and precision in the use of the term 'networks'. A broad definition of health networks that has been offered by Jeremy Shiffman, that they are "webs of individuals and organizations linked by a shared concern to address a particular health problem". In practice, the term tends to be used interchangeably with at least half a dozen others (including alliances, initiatives and partnerships). Across all of this territory of nomenclature, what we see is collaborations with diverse goals and methods of working and diverse degrees of formalization, openness and sources and levels of funding. So this is the spectrum of collaborations that I am going to include in using the term 'networks'. So why have these diverse forms of health innovation networks become of such importance in recent years? We can find some of the answers to this question by looking at the evolving landscape of the pharmaceutical industry, which has been intimately associated with the huge increase in average life expectancy we have witnessed during the last century and a half.
3	Prior to the emergence of modern pharmaceuticals, people seeking remedies for their medical afflictions were at the mercy of apothecaries who would offer treatments based on natural products or on the newly emerging synthetic products of the young science of chemistry. This was a local, cottage industry without much science base and no regulation. The transformation to the modern pharmaceutical industry was a result of two key advances – one was better science and the other was better regulation. And these advances depended on the interaction and synergy between three players: academia, and industry undertaking basic research that provided better understanding of the nature of diseases and leads to the kinds of substances that might be used to treat them; industry then taking forward the development of practical drugs; and the third actor, government, playing key roles in funding basic research, fostering academia-industry collaborations, and also setting and supervising the regulatory systems of quality, efficacy and safety to protect the patient.
4	So, the modern pharmaceutical industry looks very different, with more than 1,500 tested and approved drugs and a global industry with annual sales of s US$ 1.2 trillion in 2018. But behind this story of spectacular success, a much more complex picture has been emerging in the pharmaceutical R&D landscape.
5-7	Since the 1990s, the pharmaceutical has been undergoing some major upheavals. There has been: 1. Massive condensation, involving mergers and acquisitions, which has led to a much smaller number of companies but some of them are massive multinationals: About a dozen had market capitalizations of US$ 100 billion or more in 2018. 2. But at the same time, there has been a shift from 'vertical' to 'horizontal' structures, including the separation of research from development. This dis-integration has been a seismic shift, not only for industry but for the wider world. It has opened up new spaces for the entry of academic R&D centres, early stage biopharmaceutical companies and contract research organizations. And… 3. Since the big pharma companies were no longer creating their own leads, they began to rely on buying intellectual property rather than creating it. Whether this seismic shift in the pharmaceutical industry landscape has been a good or a bad thing has become a hotly contested area. Some saw it as a great opportunity, but by the early 2000s, there was growing concern about the impact of the on R&D performance and, as the prominent industry analyst Henry Grabowski put it, there was a persistent R&D productivity problem. John LaMattina (a former President of Pfizer Global R&D) has been more blunt, stating that the Pharma mergers have been bad for science, for patients and for medicine.
8	Meanwhile, there is an increasing number of oncoming global health challenges requiring our attention. Many are related to the state of our bodies, including the need for better diagnosis, prevention and treatment for an increasing range of disease challenges And there are many new challenges that relate to the state of the world, including a global physical and biological environment that is changing due to pollution, human activity and population growth; and a host of economic, political and social factors that impact on health and health equity. It was for this reason that, about 15 years ago, I was one of those to promote a change from speaking about 'health research' to a framing as 'research for health, to acknowledge this much wider range of determinants of health.

9	To summarise: the changing landscape of R&D for health includes changes in: • Conditions/places/spaces in which R&D for health takes place • Nature and purpose of R&D for health • Nature of health challenges Not surprisingly, the nature of health innovation networks & other collaborations has also been changing, partly in responding to all these changes in the health R&D landscape, and partly evolving in their own innovative ways. There has been an explosion in the number of networks, alliances, consortia, initiatives, collaborative projects partnerships and ventures since the 1990s – dealing with different stages of the drug development process or behaving as virtual pharmaceutical companies covering everything from basic research to clinical trials and product introduction and supply. So, this is a huge and complex scene and I will try to exemplify it and highlight some systemic issues for attention by a focus on one area which has been central: the contributions of chemistry to health innovation
10	Chemistry is often referred to as the central science and is intimately involved in all stages of disease prevention, diagnosis and treatment.
11	After the UN Sustainable Development Goals were agreed by governments at the UN in 2015, a group of us associated with the International Organization for Chemical Sciences in Development published an article in Nature Chemistry, in which we discussed the need for chemistry to make pivotal contributions to achieving sustainable development. But we said that, to do so, chemistry needs a new orientation in its priorities, approaches and practices, which we termed 'one-world chemistry'. This offers a framework which recognizes that the health of people animals and the environment are all intimately inter-connected. It proposes that chemistry should aim to be a science for the benefit of society; and requires that chemistry wholeheartedly adopts systems thinking and cross-disciplinary approaches as mainstream activities that are central to education, research and practice.
12	Later, we went on to apply systems thinking to look at the multiple ways that the chemical sciences support the health of people, animals and the environment. • They support education, research and practice in 'the chemical sciences for health'. • They support pharmaceutical and other health science industries; and also agriculture & fisheries • and they provide the basis for monitoring, protection, preservation and cleaning of the environment Together, these activities • provide us with safe, effective, affordable pharmaceutical products and other medical products and devices: • they contribute to our access to safe, nutritious food; • and they enable us to be able to work for good quality of the environment And there are regulatory systems that are intended to oversee each of these three areas which are so vital for our overall health. Together, these activities have a central contribution to make to the overall ambition of sustainable development that supports healthy people, animals and planet. But in our analysis we saw that there are three systemic fragmentations that act as inhibitors. These are disconnections in: 1. the science discipline 2. the functioning of the related industry 3. the regulatory systems related to health Let's briefly look at each of these three fragmentations in turn:
13	**1. Compartmentalization in the science discipline** For health, core chemistry (inorganic, organic, physical, analytical, theoretical) needs to interface with a wide range of other sciences that are also concerned with aspects of human, animal and environmental health. But it's extraordinary to note that the field of 'chemistry and health', does not exist as a recognised subject.

14	We have therefore proposed that 'chemistry and health' should be created as a recognised discipline, in order to: ➢ create an overall vision ➢ provide the intellectual underpinnings for education, research and practice ➢ and also to promote convergence of diverse knowledge streams that can be harnessed to enhance innovation for health Such a move would require: ➢ New partnerships of chemistry with health and environmental disciplines ➢ New networks of collaborating Departments/Institutions in teaching & research ➢ New degrees in 'Chemistry and Health'; and it will require efforts to change existing curricula. And of course, we all know how difficult it can be to change curricula that have become embedded in institutions.
15	**2. Dis-integration in the pharmaceutical industry** The second fragmentation we are concerned about is the one which I have already talked about, which has been developing in the pharmaceutical industry for the last 3 decades. The model evidently needs revisiting, since the world needs more drugs and other health products at more affordable prices for more diseases and conditions; and a system that enables achievement of the SDG goals of health and health equity for all, based on the principle of 'leave no-one behind'. Solutions will not be straightforward: the changes that this sector have undergone in the last 3 decades were driven by forces at play in the overall economic reward and innovation systems at national and global levels If countries want to have strong pharmaceutical development capacities and play leadership roles in the field, they need to play close attention to systemic elements involved and bolster critical ones, including: • ensuring strong, robust and well-designed education programmes • well-funded academic centres that can create new leads to health products • innovation hubs that foster early-stage drug development • national innovation systems and innovation financing that encourage the growth of independent middle-size companies that have options beyond buy-out when they create promising candidate products and high-value new licensed drugs Across all these areas, there is a need to foster and support networks to encourage research, development and innovation for health.
16	The third fragmentation we identify is that there are important **3. Disconnections in the regulatory sector** It's a dirty world (full of pollution) and a fake world (full of counterfeits and adulterated materials). And these things strongly affect pharmaceuticals, food and the environment. So, there is need for more effective regulation that is better coordinated and aligned across the pharmaceuticals, food and environmental sectors. Regulation consists of laws and also the policing and criminal justice systems to enforce them. Analytical science feeds into all three, determining what is <u>possible;</u> what is <u>detectable;</u> and what is <u>enforceable</u>. What is needed is a system that supports Health innovation R&D right across the pharmaceuticals, food and environment sectors. This requires that we find ways to foster and support networks to better align and coordinate regulation – including laws, standards, methods It also means that dialogue essential among all the players, including scientists, policy makers, the legal system, public, media. Two critical aspects for this dialogue are that we need: ➢ a shared, non-technical language ➢ and effective communication – for example, about the meanings of terms like 'certainty' and 'risk'.

17	So, what is needed is communication that creates productive dialogue, leading to decision-making and effective regulation and enforcement. This process needs to involve people working in the diverse but, as we have just seen, interconnected fields of pharmaceuticals, food and the environment as well as policy-makers and people from an array of national, regional and global organizations. But there are quite a lot of these. There are diverse organizations that represent groups of professional analysts and different analytical techniques; and there are national and occasionally regional bodies involved in the regulation of registration, quality and enforcement. So, with such a complex array of actors across different disciplines and sectors, how is the world going to be able to create a coherent dialogue, reconcile different views and make sense of the field? How are the scientists, policy makers and regulators going to be able to communicate with one another and act effectively together? Well, perhaps it's time to consider whether we need another kind of collaboration: a World Organization for Regulation of Food, the Environment and Drugs. This could begin as a simple network promoting coordination and fostering innovation, including in R&D. But it might conceivably eventually evolve into a body with powers – providing a truly global solution to a global problem.

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