Statement on Data and Materials Sharing and Intellectual Property in Pluripotent Stem Cell Science in **Japan and China**

INTRODUCTION

> "Tension is increasing between fairly new and pervasive policies and practices governing data and materials sharing and intellectual property in science ('proprietary structures'), and norms of openness and free exchange. While intellectual property rights (IPR) can bring private investment into areas underfunded by governments and help bridge gaps between scientific invention or discovery and useful technologies, some new and emerging policies and practices risk slowing innovation in research and development (R&D) and skewing attention toward large markets, to the disadvantage of small markets, such as those for rare diseases and in some emerging economies. This is of concern, as one central goal of the life sciences is to improve global health: our shared humanity and the potential for biological knowledge to benefit all people create this obligation. Further, the self-regulatory structures within scientific communities, as much as the legal institutions we consciously erect for science, should be responsive to this goal."[1]

In November 2010, the Hinxton Group brought together international leaders and stakeholders from the fields of stem cell science, ethics, policy and law at a meeting in Manchester, United Kingdom (UK), to address challenges arising from existing proprietary structures in pluripotent stem cell research. This meeting resulted in a consensus document titled "*Statement on Policies and Practices Governing Data and Materials Sharing and Intellectual Property in Stem Cell Science*," which identified challenges faced by stakeholders in pluripotent stem cell research and made recommendations, which are revisited below, for addressing these challenges.

While Hinxton-Manchester delegates were drawn from around the world, only a minority of the delegates to the 2010 meeting came from East Asia. Due to the marked differences between the research and regulatory contexts in East Asia, as compared with the West, it was anticipated that the 2010 consensus statement might need to be revisited in these contexts. Further, it seemed plausible that the recommendations arrived at by a mostly Western group might not be entirely transferable to countries in the East. As such, a meeting was organized in Kobe, Japan, to focus on intellectual property and data/materials

[1] Hinxton Group (2010) "Statement on Policies and Practices Governing Data and Materials Sharing and Intellectual Property in Stem Cell Science." Available at http://www.hinxtongroup.org/Consensus_HG10_FINAL.pdf.

sharing in the stem cell science communities in East Asia, with specific focus on Japan and China.

Japan and China, though they have distinctly different histories, cultures and socioeconomic contexts, together have a special role to play in the international landscape of intellectual property and the exchange of data/materials in pluripotent stem cell science. While there is a huge amount of very high-quality basic research being conducted and published by researchers in these countries, Japan and China are dramatically underrepresented in terms of patents and licensing in pluripotent stem cell innovation. In addition, these East Asian nations face unique challenges due to a younger and less developed innovation ecosystem in the biological sciences, making it generally more difficult to bring new inventions to international markets. The somewhat distinct relationship between the state and the innovation infrastructure create a unique regional innovation ecosystem. Finally, ways of thinking about IPRs appear to be different in significant ways, and Japan and China are markedly less litigious than the West [the United States (US), in particular]. In Japan, for example, patents are frequently used to guarantee freedom to operate, rather than for out-licensing or market exclusivity.

As in the 2010 meeting in Manchester, our research for and deliberations at the 2012 meeting in Kobe focused primarily on human pluripotent stem cells (embryonic stem cells, ESCs, and induced pluripotent stem cells, iPSCs), and their derivatives, rather than on tissue-specific stem cells. This is, in part, because the ability to derive human pluripotent stem cells is relatively new and because of the considerable excitement (political as well as scientific) that these cells have generated, but also because their origins and very nature create special problems relating to IPRs. Indeed, the pluripotency of ESCs and iPSCs is a major issue in terms of utility and overlapping patent claims. The youth of this area of research also means that basic protocols are still in flux, and the field has yet to produce a harmonized set of international (and, in most cases, national) standards for optimized stem cell derivation, characterization, and maintenance. The field further lacks agreed-upon parameters to qualify cells as usable in different classes of investigation (e.g., drug screening, cell-based interventions). Despite these unique aspects of pluripotent stem cells, it is quite likely that many of our deliberations and recommendations could equally apply to tissue-specific stem cells, whether these are fetal, perinatal, or adult in origin. We encourage those working on these other stem cell types to consider adopting similar measures to those advanced herein and to contribute to common resources for the exchange of data and materials.[2]

In developing this statement, we acknowledge that the diversity in patenting policy and implementation across jurisdictions makes it difficult to develop and implement common practices and recommendations globally. Further, the models of data and materials sharing

[2] Hinxton Group (2010) "Statement on Policies and Practices Governing Data and Materials Sharing and Intellectual Property in Stem Cell Science." Available at http://www.hinxtongroup.org/Consensus_HG10_FINAL.pdf.

that are relevant for ESCs may not work well for iPSCs, where it tends to be the derivation method and related information, rather than cell lines themselves, that are of most value. Finally, it must be noted that IPR policy and practice in the West (and in the US, in particular) strongly influence developing practices in Japan and China. Furthermore, strategies and recommendations developed in the West may help to promote progress in Japan and China. That said, the local context matters greatly, and the opportunities created by the regional environment in Japan and China provide valuable lessons for the global development of this field.

CHALLENGES AND CONSEQUENCES

Japan and China are among the world's most productive nations in terms of stem cell research (as measured by number of peer-reviewed publications), but both face a range of challenges in their efforts to secure and exploit IPRs, and to develop clinical and other applications for domestic and global markets. Some of these appear to be transient, soluble problems, and are being addressed by these countries' ongoing initiatives to modernize and expand their systems of IPR governance. Other challenges appear to be consequences of differences in priorities, norms, and attitudes toward such fundamental issues as the role of litigation, the public right to healthcare, or the relationships between government, industry and academia. These challenges and consequences fall into two broad categories, *Intellectual Property* and *Regulatory Issues*, as outlined below.

Intellectual Property

In both Japan and China, intellectual property policies are relatively new and continue to evolve. China, for example, enacted its first modern patent law as recently as 1984, and has amended this multiple times in recent years, while Japan established policy promoting the commercialization of products developed in government-funded academic research as part of the Industrial Revitalization Special Law, fully implementing relevant provisions only in 1999. There have also been efforts to harmonize with world standards through accession to global conventions. Japan was one of the original signatories to the World Intellectual Property Organization (WIPO) Convention in 1967 and to the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) in 1995. Since 1983, the Japan Patent Office has actively engaged in a technical consultative process known as the Trilateral Co-operation, with the US Patent and Trademark Office and the European Patent Office, developing global patent standards for emerging fields like biotechnology. China signed the WIPO convention in 1980 and the WTO TRIPS Agreement in 2001. Despite rapid developments, China faces challenges related to still-developing capacity and expertise in this area, as compared to the more robust expertise in the West. This disparity may be the result of the shorter history of modern IPR infrastructure, relative comparative advantages of their national industries' R&D capacities, as well as normative differences, as described below. It will be important for both Japan and China to involve scientific experts more closely in efforts to standardize, reform, and rationalize patent laws and their implementation. Of particular importance will be issues relating to "patentability"; that is, standards for what may and may not be patented.

It appears that, at least among those working in non-commercial or public sector research, the level of awareness of and attention to IPRs tends to be lower than in Western countries, such as the US (with a number of clear exceptions). Perhaps as a result of unfamiliarity, distrust of systems for governance and adjudication, or simply differences in cultural attitudes or social norms, secrecy appears to be a relatively more common mode of protecting researchers' raw IPRs, as opposed to more formalized legal systems of protection, such as patenting.

In some cases, patenting may be seen as an end in itself, especially in systems such as China's in which researchers' patent applications are used as an evaluation metric in promotion decisions or for symbolic reasons; this can lead to inefficiencies and unnecessary costs for institutions sponsoring the applications. We further note that while China has strengthened its protections for intellectual property in recent years, its enforcement of IPR laws remains inconsistent, which may emerge from a more tolerant view toward infringement, or an insufficient ability to enforce existing laws uniformly.

Regulatory Issues

The process of policy development in both Japan and China appears to be slow, although for different political and structural reasons. Implementation of existing policies, laws and regulations is compounded by jurisdictional uncertainties, difficulties in coordination across separate ministries and agencies, and inconsistent local enforcement (the latter being a particular issue in China). Reform efforts may also meet with opposition from entrenched interests, causing delays in the pace of change. That is, there is conflict between different stakeholders and structural factors that work to promote or to resist reform.

Policy-setting and regulatory authorities in both nations tend to be highly centralized, and may fail to fully embrace multiple perspectives, including those of independent experts, in their decision-making processes. In the sciences, this is compounded by the relative scarcity of non-governmental funding sources, and the comparatively weaker roles played by civil society groups, such as patient advocacy groups and independent scientific academies, in determining state policy.

While not strictly a problem of regulation, it appears that at present the commercial sector in the pluripotent stem cell space remains relatively smaller in both Japan and China, which may become an issue in the future should research give rise to promising applications or avenues for development. At present, China in particular is striving to establish and enforce regulations governing the clinical testing of stem cell technology to ensure patient safety and clinical efficacy. In contrast, inefficiencies in the testing and approval systems for medical products in Japan have resulted in a significant "drug lag." We note several recent cases in which a biomedical technology developed in Japan was tested first in the US or EU, due to concern over costly delays in the Japanese regulatory system. Such delays may be due in part to a cultural tendency to risk aversion in Japan, although we note that this may in some cases have benefits in emphasizing safety over speed. With specific regard to stem

cell research and applications, the systems for ethics review of research protocols and clinical trials are still under development, and remain variable; this, however, is not unique to the region and may improve rapidly as the volume of scientific research and experience with oversight grows.

OPPORTUNITIES

Despite the many challenges discussed above, participants at the Kobe meeting also identified a number of distinct opportunities for pluripotent stem cell R&D within Japan and China. These advantages are, in particular, relative to the US system of strong IPRs combined with market-led development of therapies that promise the highest profit margins for their developers, but not necessarily the broadest public health benefits.

First is the quality and size of the scientific infrastructure and workforce present in the areas of cell biology, developmental biology, and regenerative medicine in both Japan and China. Examples cited for China included the Chinese Academy of Medical Sciences, with 12,000 researchers nationally, and the Center for Stem Cell Research, established in 2010. Examples cited for Japan include several research clusters in the life sciences, with the Kyoto life-science sub-cluster already innovating in stem cells and the Kobe life-sciences sub-cluster being well integrated from basic research to translation. The impression is that networked research establishments of this sort within both countries are of sufficient scale and complexity to be able host the kind of collective action needed to effectively and efficiently develop stem cell innovations.

Second, while stem cell innovations may require coordination of multiple components of a complex system, we note the magnitude of government investments in strategic initiatives in Japan and China, together with a strong government role in the national business and economic landscape, may afford companies in these countries the financial strength to invest in, coordinate, and shepherd these complex innovation projects. In addition, companies that are favored with strategic national investments of this sort are likely to enjoy advantages in access to regulatory systems. This combined mastery of systems complexity and regulatory access may give such companies better control over the technologies they develop, despite the relatively weaker IPR environment.

Third, we note that companies in Japan and, increasingly, in China, generally enjoy a global comparative advantage in high quality manufacturing capacity. While more speculative, given the current state of development of stem cell products, it is recognized that if large scale, high quality production of stem cell products is required, these two economies are potentially in a relatively good position in terms of human capital, know how, and business expertise to build and run such manufacturing facilities.

Finally, there are potential opportunities given the national health care systems of China and particularly Japan, with a national body negotiating access to technologies and therapies on behalf of patients and a national system coordinating services at significant

scale – a distinguishing feature from the US, but not the West, generally. These conditions may allow development of more complex point-of-service therapies (a likely therapeutic model for cell-based interventions) and more focused on ensuring patient access to novel treatments, rather than focusing on development of stand-alone blockbuster products, the therapeutic model that appears to result from the incentive system created by strong IPRs.

2010 HINXTON GROUP STATEMENT RE-EXAMINED | JAPAN AND CHINA

The consensus statement resulting from the Hinxton Group's 2010 meeting in Manchester included five sets of recommendations aimed at addressing the challenges identified in relation to the proprietary structures affecting pluripotent stem cell science internationally. Given the particular regional challenges and opportunities emerging from the 2012 meeting in Kobe, the delegates re-examined the 2010 recommendations to consider whether they were appropriate to the regional contexts in Japan and China and were adequate to address both the local challenges and opportunities.

1a. Establish a central hub for accessing global stem cell registry information

The aim of this recommendation was to increase access to information and facilitate data and materials sharing amongst the global scientific community by providing a publicly available central information hub. This could be achieved through building on existing registries to create a single portal to a set of knowledge resources, which would be collectively owned and maintained. Such a resource would require inter-institutional cooperation and coordination, resources for set-up and maintenance, minimum required data and standard data formats. Participation would be encouraged through incentives or constraints imposed through funding bodies and publication requirements.

Within Japan and China, current mechanisms for accessing information (such as existing registries) appear to be adequate, but they will need to keep pace with the development of new cell lines. Although a centralized information portal might be of added value, the initiative and resources to develop this would need to be generated and/or coordinated at the national or international level.

Language barriers were also identified as a potential difficulty in creating a global information repository; while relevant databases exist in Japan, they are in Japanese only. There is some regional precedent for setting up successful information resources across national and linguistic boundaries: the WHO International Clinical Trials Registry Platform requires the minimum data set to be supplied in English, and participants include Japan, China, India and Korea; the existing Chinese national registry coordinated between four stem cell banks includes information and guidelines in both Chinese and English. The costs of translation in developing and maintaining such a resource, however, are significant.

1b. Establish a central hub for accessing information about stem cell patents

Manchester delegates were concerned about the complexity of the stem cell patent landscape, the difficulty of obtaining full and accurate information about the stem cell

patents, the variation in patenting standards across jurisdictions and the consequent uncertainty and costs of navigating the 'patent thicket'. A centralized data resource for global stem cell patent information could help to address these problems. As in Recommendation 1a, inter-institutional cooperation would be required to establish and maintain this hub. Additional resources would also be needed to address knowledge gaps.

In Japan and China, it appears that in general (though not uniformly), there is less emphasis on patenting within the stem cell field than in the West, and many do not perceive patents as hindering freedom to operate to a substantial degree; thus, access to patent information is not currently a foreground concern for most. This is likely to change, however, as the regional and international patent landscape evolves, and significant work to this end has begun in Japan [for example, by the Ministry of Education, Culture, Sports, Science and Technology (MEXT)]. It may, therefore, be beneficial to set up mechanisms to gather and maintain this information sooner rather than later, particularly if it is relatively inexpensive to do so.

2. Encourage, support and coordinate international human stem cell banks and human tissue and cell repositories

Where Recommendations 1a and 1b relate to information about stem cell lines and patents, this recommendation was aimed at facilitating the sharing of materials through stem cell banking, enabling streamlined materials sharing, reduced transaction costs and difficulties associated with material transfer agreements, and requiring the establishment of global scientific and ethical standards (particularly regarding provenance information and informed consent). These efforts could build on existing stem cell banking initiatives at both the national and international level, and begin with a small collection of cell lines.

Within Japan, the small number of cell lines being derived makes banking a feasible option, and there is an existing Japanese pluripotent stem cell bank; China also has multiple hESC banks. There may be regional as well as intra-national opportunities to coordinate local stem cell banking resources and to connect with banks in other countries. However, national regulations may make it difficult to share cell lines across national boundaries, or to participate in international stem cell banking initiatives. Japanese regulations prevent local hESC lines from being deposited into prominent stem cell banks outside the country, such as the UK Stem Cell Bank. China likewise has strict policies governing biological samples donated by Chinese citizens and the cell lines derived from them, making it difficult to share materials internationally. International variation in policy and attitudes towards profit/non-profit uses may also hinder efforts to develop internationally-coordinated stem cell banking initiatives. It should also be noted that the advent of induced pluripotent stem cell technology, which allows for the relatively simple derivation of large numbers of pluripotent stem cell lines, has also raised issues for the viability of the cell banking models developed for human embryonic stem cell lines, a comparatively scarcer resource.

3. Develop and institute incentives for data and materials sharing through publication, participation in information hubs, and other mechanisms

The success of the above recommendations will depend upon the willingness of scientists, research institutions and governments to participate in such collective action initiatives. The Manchester statement recommends the development of incentives for sharing, including through requirements from funders and publishers, with the assistance of research institutions and regulatory bodies, and with input from scientists regarding scientific standards and behavioral norms.

In this regard, the balance of motivations within the culture of science in Japan and in China, either to share or withhold data/materials, may be somewhat different to that in the West, meaning that a different balance of incentives is required in this regional context. The significance of financial gain as an incentive for science; the role of commercial interests in academic research; and the importance of protecting the potential for profit are all likely to vary by culture and social norms. While there is a relatively high level of commercial activity and a strong financial driver for stem cell science in the West, scientific recognition (receiving academic credit for the work) and publication priority are highly valued in Japan and China. Protecting the interests of individual scientists and research groups in this respect, for example through imposing a 'grace period' or 'priority period' for the use of shared data/materials, would thus be a valuable incentive. Difficulties may arise, however, particularly with respect to cell lines, in determining the appropriate start point and duration of the priority period.

Academic status can itself be an incentive to share data and materials: publishing data and making information and cell lines readily available from an early stage can establish one's work as a standard in the field, leading to greater recognition. This could also be supported through funding, either as a reward for academic excellence, or as a start-up investment to promote research that will gain recognition and become established as a standard, thereby becoming self-sustaining. An example of this is the National Bioresource Project for *C. elegans*. This core facility creates, collects, stores and distributes *C. elegans* deletion mutants, has been a tremendous resource to the genetics community, and was initially funded by the Japanese government; similarly, the structure of Chinese governmental research funding is aimed at setting up large research initiatives with the expectation that these will become self-supporting.

The varying utility of incentives to promote sharing at national and global levels indicates an underlying tension between national and international interests. With respect to materials sharing, for example, China has a central clearing-house to facilitate sharing at the national level, but national policy restricts the international distribution of samples, which are considered Chinese intellectual property. The development of incentives to promote both national and international sharing will need to take account of these factors.

4. Explore options for formal collaborative networks, patent brokering, and formation of patent pools when those mechanisms for collective management of intellectual property can move the field forward

This recommendation was aimed at investigating ways to reduce the transaction costs (both in terms of financial resources and time) associated with IPRs in the area of pluripotent stem cell research, and to alleviate uncertainty, with the objective of facilitating R&D. A number of specific mechanisms were suggested as potential options for collective management of IPRs. As it is unclear which model of innovation and IPR development PSC-based therapies will or should follow, it is necessary to explore multiple strategies that may be successful in promoting the progress of science and innovation.

As elsewhere, stem cell research and IPRs in Japan and China are at an early stage, where it is not yet evident whether and which strategies will offer an advantage in developing research and applications, leaving the possibilities ripe for exploration. With this in mind, more discussion between major stakeholders should be promoted. Within Japan, organizations and institutes that are major holders of PSC-related IPRs might provide leadership in this area, with the dual motivations of expediting translational research, and securing the country's competitive position internationally. This suggests an opportunity for regional leadership that remains unexploited and in which local institutions could take the lead.

5. Adopt licensing practices and patent policies that promote fair, reasonable, and nondiscriminatory (equitable) access to knowledge and health care applications

The aim of this recommendation is consonant with the goals and norms (both implied and expressed) of science, international policy statements on health and human rights, and numerous policy statements of professional bodies and scientific societies. The Manchester statement calls for the implementation of certain licensing and patenting practices to achieve this, including licensing provisions that protect rights of access, obligations on government-funded research institutions to make their IPRs public, and action by international patent policy-makers to evaluate the effects of current patenting processes with respect to this aim.

The fact that stem cell science in Japan and China is predominantly government-funded, with comparatively little investment by industry, strengthens the imperative for any IPRs generated to be used for public benefit, on the grounds of reciprocity. This may not always mean broad, non-exclusive licensing (in some cases exclusive licensing may promote greater utility). Although licensing decisions may be made on a case-by-case basis, public benefit should remain a primary consideration.

Both Japan and China already have policies in place towards this end, with respect to licensing of PSC-related IPRs. In Japan, guidelines including the Council for Science and Technology Policy's "Guidelines for Research Licenses for Intellectual Property Rights Stemming From Government-Funded Research and Development at Universities, etc. (May 23, 2006)" and its "Guidelines for Facilitating the Use of Research Tool Patents in the Life

Sciences. (March 1, 2007)", while in China, the Ministry of Health has issued guidelines relating to in-country licensing. As evidence from the West shows, however, the mere existence of policy is not always sufficient to guarantee uniform practice; the extent to which policies are implemented must also be considered. Moreover, conflicts may arise between national and international licensing practices.

While international guidelines, such as the AUTM's statement "In the Public Interest: Nine Points to Consider", may be helpful in shaping national policies with respect to licensing, international practices can also influence national policy in ways that exacerbate tensions between national and global interests. For example, the US Bayh-Dole Act stipulates that licensing decisions should benefit (US) national industry; the Japanese equivalent lacks this provision, creating a transnational asymmetry in this regard.

CONCLUSIONS

Goals and Values

The purpose of this Hinxton Group meeting in Kobe was to identify challenges facing the stem cell field in Japan and China related to proprietary structures in science. We also sought to analyze this stem cell landscape against the recommendations of the 2010 Hinxton Group statement, which was geared toward a more global context. As outlined above, the Hinxton Group delegates in Kobe endorsed the major ideas of the 2010 statement as being useful and broadly applicable to Japan and China. Even so, novel challenges emerged for these East Asian nations.

In examining challenges and opportunities in this regard, delegates identified specific policy ideas, such as the need to redouble efforts at national standardization and harmonization, to maximize the use of patented resources through mechanisms such as broad non-exclusive licensing, or, when necessary, narrowly targeted exclusive licensing, and to streamline state regulatory structures. However, we felt that to issue a mere policy statement, which fails to articulate the deeper values and ultimate goals of Japan and China, as much as the rest of the world, would be to lose an important opportunity: for what is speculating upon the means, without investigating the ends, of science policy?

Accordingly, the Kobe group spent some time – subsequent to identifying challenges and opportunities, and considering the 2010 Hinxton statement – to reflect on the values and goals which motivated the entire discussion, both explicitly and tacitly.

We used an inductive, rather than deductive, approach to examining the normative basis of the Japanese and Chinese stem cell concerns. In other words, the group did not start by positing general norms, from which policies followed. The movement between goals and policies was fluid. We defined a set of challenges and opportunities, and then worked to identify values and goals embodied therein. In turn, this helped the group sharpen its definition of the challenges and formulate potential solutions. A good example of this is the

identification of the important role of civil society in the formation of life science regulation, reflected below.

Because it was an antecedent to Kobe, the 2010 Hinxton delegates could not have adopted the following list of values and norms. However, one will quickly recognize a consistency and deep resonance between the norms stated by Hinxton-Manchester and Hinxton-Kobe. This fact, in itself, provides important evidence that although states and regions may be separated by particular national goals, there is an abiding convergence in the imagined goods of science.

Health and Clinical Care

In the Manchester statement, the ideals of global health and justice provided a preamble. Discussions at Kobe also voiced serious concern for *health and clinical care.* This emerged in a number of ways. First, leaders in the field of stem cell research in Japan, it was discussed, have made concerted efforts to set liberal licensing policies that would not allow patents to get in the way of potential future clinical applications. Further, both Japan and China evince a deep commitment to health as entailed by their national health care systems. Innovation in these countries occurs in the context of national commitments to the health of its citizens, and as a practical matter will make access equitable.

National and International Innovation

The goal articulated most strongly in Kobe was the strengthening of *national stem cell innovation* in Japan and China and their national innovation systems more generally. R&D was discussed as a good in itself, assumed to advance human welfare within and utility for those societies.

Implicit in choosing to analyze the challenges of R&D in East Asian countries, as opposed to the world as a whole, is an idea that what benefits regional economies will benefit the world in general. Thus, just as advancing national innovation systems was an important goal, so too was advancing *international innovation systems*. The group recognized, however, that the goals of national innovation and global innovation might sometimes come into conflict. The articulation and consideration of both, however, can only foster a more symbiotic relation between national and global innovation. A shared commitment to scientific progress, as discussed below, may be an important element in that symbiosis.

Regulatory Values & Goals

It was recognized in Kobe that R&D in the life sciences encompasses a highly regulated set of activities, especially as health products move into the clinic. Accelerating the pace of stem cell science, then, also demands optimizing the regulatory system. But as our conversation showed, good policy is not a function of optimizing a single variable. Multiple goals and values underlay our discussion of regulations, and our interest in speeding R&D must be balanced against other societal interests. The major values and goals of regulation as articulated in the meeting were:

1. *Efficiency*. Regulation needs to be more streamlined and less bureaucratic.

2. *Rights and interests of research subjects, patients and donors*. The R&D process should respect the interests and rights of individuals contributing cells and pioneering new therapies. Conflicts of interest are especially important to manage.

3. *Rights and responsibilities of key stakeholders.* A larger set of actors – including civil society groups, scientific communities, disease advocacy groups, etc. – should be encouraged to participate in the policy process, and in fact have a societal obligation to do so.

4. *Product safety and efficacy*. Government regulators must ensure safety at the levels chosen by society, and make sure that new therapies are efficacious.

5. *Appropriate role of science*. Governments must involve scientific advisors to ensure that regulation is based in the best available science and is responsive to concerns in the laboratory. However, regulation requires both technical expertise and societal and political choice, in part to enact the above values. As such, scientific input should be accompanied by the involvement of regulators with political accountability.

6. *Procedural due process*. An important goal will be to standardize better procedures within the regulatory process to help affect all of the items above, especially #3.

Global scientific progress

The scientific enterprise benefits from openness, which helps to ensure its advance across national and international scientific communities. To the extent possible, there should be collaboration across the public and private sectors, and national boundaries, to keep information in the public domain and to facilitate the responsible progress of science. Further, as institutions historically committed to generating universal knowledge and serving the public, universities are in an important position to help ensure – through their IPR policies – that their own licensing processes will not hinder science. There will always be tensions between national and international and between public and private, with regard to innovation and the proprietary structures that promote it. Within the biomedical sciences, the key is to strike a balance that both promotes innovation and improves global health.

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