Institute on Science for Global Policy (ISGP)

Science and Governance:
Focus on the Genomic Revolution

Conference convened by the ISGP in partnership with the Parliamentary Office of Science and Technology, within the Houses of Parliament, London, United Kingdom, September 6, 2013

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An ongoing series of dialogues and critical debates
examining the role of science and technology
in advancing effective domestic and international policy decisions

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Introduction

Dr. George H. Atkinson
Founder and Executive Director, Institute on Science for Global Policy
and
Professor Emeritus, Department of Chemistry and Biochemistry and
College of Optical Sciences, University of Arizona

Preface

The contents of this book were prepared from material presented at an international conference on the Genomic Revolution convened by the Institute on Science for Global Policy (ISGP) on September 6, 2013, in cooperation with the United Kingdom Parliamentary Office on Science and Technology (POST). The conference was held within the Houses of Parliament at the invitation of POST. This ISGP conference was part of the ISGP program on **Science and Governance** and engaged individuals who are currently in or were recently members of legislative and parliamentary bodies.

The processes underlying all ISGP conferences begin with the recognition that a scientific topic such as Genomics has emerged on the international stage with advances that promise immense opportunities to improve the human condition. Simultaneously, it is recognized that discussions on Genomics challenge many cultural, ethical, and economic topics throughout societies worldwide. From the ISGP perspective, decisions within societies concerning how to appropriately incorporate such transformational science into public and private sector policies require candid debates that highlight the credible options developed by scientific communities throughout the world. Since Genomics can potentially have significant impact worldwide, it deserves attention from both domestic and international policy makers from a wide range of disciplines. ISGP conferences offer those rare environments where such critical debates can occur among credible scientists, influential policy makers, and societal stakeholders.

Based on extensive interviews conducted by the ISGP staff with an international group of subject-matter experts, the ISGP invited three highly distinguished individuals with expertise in the scientific and societal impact of Genomics to prepare the three-page, policy position papers to be debated at the London conference. Each author was asked to summarize his paper in the initial 5 minutes of a 60-minute

debate period. These three policy position papers, together with the not-for-attribution summaries of the debates of each paper, are presented in this book.

Given the limited time available for legislators and parliamentarians to participate, this one-day conference used a modified version of the normal ISGP debate and caucus format. Following the three debates of each policy position paper, three Caucus Leaders with legislative experience were asked to make short (10 minute) statements concerning conclusions they would endorse. These statements are included here under the names of each Caucus Leader. A general 120-minute caucus discussion involving all participants and focused on identifying areas of consensus and actionable next steps then commenced. A not-for-attribution summary of the general caucus discussion and the areas of consensus and actionable next steps emerging from the entire caucus process are presented here.

Current realities

While the material presented here is comprehensive and stands by itself, its policy significance also can be viewed within the context of how domestic and international science policies have been, and often currently are being, formulated and implemented. While many of our most significant geopolitical policy and security issues are directly connected with the remarkably rapid and profound S&T accomplishments of our time, many societies struggle to effectively use S&T to address their specific challenges. Consequently, it is increasingly important that the S&T and policy communities (public and private) communicate effectively. Recent history suggests that most societies would benefit from improving the effectiveness of how scientifically credible information is used to formulate and implement governmental and private sector policies, both domestic and international.

Specifically, credible S&T information needs to be concisely presented to policy communities in an environment that promotes candid questions and debates led by those nonspecialists directly engaged in policy decisions. Such discussions, sequestered from publicity, can help to clarify the advantages and potential risks of realistic S&T options directly relevant to the societal challenges being faced. Eventually, this same degree of understanding, confidence, and acknowledgment of risk must be communicated to the public to obtain the broad societal support needed to effectively implement any decision.

The ISGP has pioneered the development a new type of international forum designed to provide articulate, distinguished scientists and technologists opportunities to concisely present their views of the credible S&T options available for addressing major geopolitical and security issues. The ISGP conference on

Genomics in the series on **Science and Governance** described in this book is the first effort to bring this model to those actively engaged in the legislative and parliamentary processes leading to policy decisions.

All ISGP programs rely on the validity of two overarching principles:

1. Scientifically credible understanding must be closely linked to the realistic policy decisions made by governmental, private sector, and societal leaders in addressing both the urgent and long-term challenges facing 21st century societies. Effective decisions rely on strong domestic and global public endorsements that motivate the active political support required to implement progressive policies.
2. Communication among scientific and policy communities requires significant improvement, especially concerning decisions on whether to embrace or reject the often transformational S&T opportunities continually emerging from the global research communities. Effective decisions are facilitated in venues where the advantages and risks of credible S&T options are candidly presented and critically debated among internationally distinguished subject-matter experts, policy makers, and private sector and community stakeholders.

Concluding remarks

As a not-for-profit organization, the ISGP has no opinions nor does it lobby for any issue except rational thinking. Members of the ISGP staff do not express any independent views on these topics. Rather, ISGP programs focus on fostering environments that can significantly improve the communication of ideas and recommendations, many of which are in reports developed by other organizations and institutes, to the policy communities responsible for serving their constituents. ISGP programs are designed to help ensure that S&T understanding is integrated into those real-world policy decisions needed to foster safer and more prosperous 21st century societies.

Conference conclusions

Area of Consensus 1

The current food supply system is not viewed as capable of providing access to the amount of quality food required to maintain healthy societies for the rapidly increasing populations found in essentially all countries, whether primarily food-producing or food-consuming. The sustainability of future food supply systems must be significantly improved primarily by increasing productivity through innovative agricultural practices based on scientific advances that recognize specific demographic, cultural, and population changes.

Actionable Next Steps

- Societies and governments must substantially increase investment in basic agricultural research, and create incentives for companies and academic institutions to undertake research projects and technological development directly connected to enhanced commercial productivity.
- Intellectual property regimes for agricultural biotechnology must be adjusted to balance the need to protect the benefits accruing to the groups investing in the research itself with the need to ensure the availability of innovative products to the widest markets, especially in less-affluent countries.

Area of Consensus 2

The application of the precautionary principle for the development and adoption of food, agricultural and pharmaceutical products, including those derived from genomic approaches, must be reevaluated on the basis of credible scientific understanding. The risks of inaction (i.e., the opportunity cost) must be balanced with the potential risks of action and be considered as a critical element in all evaluations used to reach policy decisions involving the precautionary principle.

Actionable Next Steps

- Risk-based approaches, in which the risks of acting are balanced against the risks from doing nothing, need to be essential components of all

decisions using the precautionary principle, especially with respect to food, nutritional, and pharmaceutical products. A balanced approach to such policies is critical when products are made available in less-wealthy countries where the risks of inaction are severe (e.g., food and water shortages, consequential overuse of chemicals, increased levels of pests and pathogens).

- Difficulties in applying risk-based approaches in certain countries (e.g., France) must be examined in the context of social, cultural, and political norms (e.g., risk-averse society, role of government to protect citizenry) where decisions need to include input from social science communities.
- The inability to accurately balance the opportunity costs of inaction with the perceived costs of a specific action can have significant national, economic, and/or political security consequences. Recent history has demonstrated that the application of the precautionary principle to issues related to food, agricultural, and pharmaceutical products have had unintended, and often negative, impacts on national interests, especially in less-wealthy countries.

Area of Consensus 3

While the enormous explosion of data available from genomic research and testing is among the most important elements influencing the cost of health care, it remains unclear whether these changes will be negative or positive relative to the anticipated reduction in health care costs associated with the introduction of genomics technologies. An accurate understanding of the impact of genomics in general is a critical component that requires urgent examination to provide policy decisions with credible information.

Actionable Next Steps

- Justification for how genomics can drive health care change must expand beyond solely reducing costs, which is an issue yet to garner wide support.
- The number of professionals trained in properly interpreting and applying genomic information, and the educational infrastructure to do so, must be dramatically expanded before the benefits of genomics can be realized by society.

Area of Consensus 4

Public confidence in genomics will require a major effort by trusted sources to accurately communicate the risks and benefits of genomic technologies.

Actionable Next Steps

- Public confidence in the results from genomic data and even in the technologies used to obtain genomic information needs to be improved through a major effort to communicate the basic issues associated with personal privacy of genomic information and the degree of uncertainty associated with the results.
- Social scientists need to be included in the design, implementation, and translation of genomic research and its communication to the public, including the balance between potential or perceived risks and demonstrable benefits.
- Improving public understanding of the issues relating to genomics will require a wider program to increase the public understanding of and respect for the results emanating from science and technology.

ISGP conference program

Thursday, September 5

17:30 – 19:00 Reception
Westminster, London

Friday, September 6

The entire ISGP conference program takes place within the Palace of Westminster and the preceedings begin promptly at the stated times.

08:00 Registration *(Jubilee Room)*

08:00 – 08:30 Coffee *(Jubilee Room)*

08:30 – 08:45 Assemble *(Committee Room 15)*

08:50 – 09:00 Introductory Remarks
Dr. George Atkinson, Executive Director and Founder, Institute on Science for Global Policy (ISGP)

Dr. Chris Tyler, Director, Parliamentary Office of Science and Technology (POST)

Presentations and Debates

09:00 – 10:00 **Dr. Roger Beachy, Washington University in St. Louis, United States, and Global Institute for Food Security, University of Saskatchewan, Saskatoon, Canada**
Genomic Sciences for Agriculture, Food, and Nutrition

10:00 – 11:00 **Prof. Ian Crute, Agriculture and Horticulture Development Board, Kenilworth, United Kingdom**
The Genomic Revolution and Sustainable Management of Infectious Plant Disease: Aligning Policies and Objectives

11:00 – 11:30 Break

11:30 – 12:30 **Dr. Leroy Hood, Institute for Systems Biology, Seattle, Washington, United States**
The Emerging Landscape of Medicine and Health Care

12:30 – 14:15 Lunch *(Churchill Room)*
Remarks: **Dr. Julian Huppert,** Member of Parliament, House of Commons

14:30 – 15:00	**Caucus Summaries** Three 10-minute commentaries on Areas of Consensus and Actionable Next Steps by caucus leaders: **Prof. the Baroness Ilora Finlay of Llandaff,** Member of Parliament, House of Lords **Mr. James Kolbe,** former Member, U.S. Congress **Dr. Julian Huppert,** Member of Parliament, House of Commons
15:00 – 17:00	**Caucus Debate** Questions, answers, and commentary by principal debate participants and audience to formulate Areas of Consensus and Actionable Next Steps
17:00 – 17:15	Closing Remarks **Dr. Chris Tyler,** POST **Dr. George Atkinson,** ISGP
17:15	Adjournment
18:30 – 20:30	Reception and Dinner *Westminster, London*

Genomic Sciences for Agriculture, Food, and Nutrition**

Roger N. Beachy, Ph.D.
Professor of Biology, Washington University in
St. Louis, Missouri, United States
Executive Director, Global Institute for Food Security,
University of Saskatchewan, Canada

Summary

From their inception, genomic sciences have been applied to plants, animals, and microbes used in food and agriculture. Genomic sciences are useful for understanding how cells work, how seeds are formed, how nutrition is absorbed by roots, and how plants and animals respond to pests and diseases, extreme weather, and changes in climate. Genomic studies have also discovered the variations in traits occurring in crop and noncrop plants that are used by breeders with DNA-based markers to develop varieties with preferred traits. When useful traits cannot be found, seeds are sometimes altered (mutagenized) to create genetic diversity. Techniques for genetic engineering are also used to direct mutations to specific genes or to introduce genes for desired traits, as is done in genetically modified (GM) crops. Crops and foods developed through genetic modification technologies, now grown in more than 29 countries, have improved productivity and farmer profits while maintaining high food and environmental safety records. Widespread suspicions regarding GM crops are based largely on unsubstantiated fear and mistrust rather than on sound scientific principles. These suspicions have weakened political will by discrediting the science of agriculture at a time when many societies are struggling to meet the demands of growing populations, climate change, and an expanding bioeconomy. Advanced genomic sciences, coupled with good agrological practices and solid science-based policy decisions, will be required to substantially reduce or eliminate global insecurity in food and nutrition and to secure a vibrant global agriculture economy.

Current realities

Food insecurity is an ongoing reality for many people around the globe. Unlike the situation through to the early 1990s, in which there were food surpluses in wealthy, agriculture-rich countries, the world is currently experiencing chronic shortages of commodity grains because of unpredictable changes in weather patterns, poor

seed quality, and unsustainable agricultural practices. The Food and Agriculture Organization (FAO), the International Food Policy Research Institute (IFPRI), and other international bodies have predicted that worldwide agriculture production must increase by at least 70% by 2050 to meet the increased demands brought on by global population growth, coupled with increased urbanization and wealth, and a growing demand for animal-based foods. In recent years, uncertainties in production have resulted in the imposition of trade policies that limit export of excess production, further exacerbating global food shortages. In recognizing these challenges, G8 and G20 leaders placed agriculture and food security issues high on the list of priorities in 2011 and 2012. The 2012 FAO report on food security reported encouraging progress through 2008 in meeting the Millennium Development Goal of halving food insecurity by 2015. Unfortunately, food insecurity has increased since 2008. The FAO also noted an important role for agriculture in building rural economies and highlighted reduced poverty in countries where agriculture is encouraged.

Although genetic advances in food and agriculture are rapid, translation to products and impacts is slow. At the same time that debates about achieving sufficiency in food and nutrition are occurring, advanced genomic knowledge is revealing solutions to increase food production, improve the agro-ecology, and improve food safety. Plant breeders have changed their approach to generating new varieties in the hope that they will help to reduce food shortages caused by poor yields. While random selection of natural or induced genetic mutations was the primary source of diversity in the past, genetic information is now regularly used to increase the rate of success in plant breeding and speed up development of new plant varieties. When "induced" or natural genetic diversity is not sufficient, scientists are using genetic engineering to add new genes to derive crop varieties resistant to diseases, insect pests, and heat and drought conditions, among other traits.

While scientific progress in crop improvement during the past decade has been remarkable, there has not been sufficient progress in fundamental research to lead to the increased levels of production that are required to achieve global food security in the near future. The situation has been exacerbated by flat or declining levels of funding for the basic research upon which the food and agriculture sectors rely. Recent studies in the United States and the United Kingdom chronicled the flat or decreasing funding for agriculture sciences in the public sector and suggested that the lack of progress in increasing yields of wheat, barley, soya, and other staple crops are due to reduced research funding.

Unfortunately, the translation of genomic knowledge into consumer and environmental benefits is much slower than necessary, particularly for benefits

of crop varieties that are conferred by genetic engineering technologies. From the outset, regulatory agencies took a cautious approach to GM technologies and recommended a complex regulatory pathway for the approval of GM varieties before commercialization. The new pathway established in the U.S. included regulatory oversight to guard against unknown and unpredicted consequences that might be caused by genetic engineering. Other countries imposed regulatory oversight processes different from the U.S., which involved additional reviews that are not synchronized with those conducted in the U.S. These regulatory hurdles significantly inhibit the importation of GM products and the access of farmers and producers in nonadopting countries to genomic advances. When regulatory processes for GM crops were put in place in 1987 it was expected that they would be phased out over time as familiarity with the science and products developed increased; however, the opposite has happened. Existing regulatory structures and asynchrony of approval favor large companies over small innovative companies and university researchers, allowing the development of seeds with high-volume sales over seeds of crops occupying fewer acres (e.g., vegetables and fruits).

Consumer acceptance of crops developed via genetic engineering varies widely between the 29 countries that produce GM crops (on more than 170 million hectares) and those that do not produce them. Even where GM technologies are adopted, vocal anti-GM groups demand that GM technology be halted or that GM products be labeled as such. Seed companies and independent scientists counter with studies that demonstrate both safety and efficacy of the new products in providing benefits to the environment and food that is as safe, if not safer, than older varieties. The impacts of these differences are reflected in current trade negotiations between the U.S. and Europe where GM agriculture products are contentious. While GM products are viewed as safe in the U.S., European leaders have imposed trade restrictions because they are less convinced that the scientific data is sufficient to ensure safety of the foods and the agro-environment. Nonetheless, the European Union has spent more than £300 million on studies that have confirmed safety of GM crops.

Scientific opportunities and challenges

Laboratory researchers use genomic sciences to understand the "whys and hows" of plants and animals. Why do some plants and animals resist certain pests and disease, or drought and heat conditions, while others do not? How do plants make certain beneficial substances, chemicals, and other materials? How do some crops make the nitrogen fertilizer they need while others do not? Why do plants grow better in some soils than others? Answers to these types of questions are as complicated as questions in biomedical sciences and require similar advanced

scientific understanding and technologies. Scientists and technologists are applying information gained through genomic sciences to answer such key questions in agriculture.

The application of genomic sciences in agriculture can provide many advantages, including higher yielding crop varieties with increased tolerance against drought and heat and crops that use chemical fertilizers more efficiently, with resultant environmental advantages. This science makes it possible to develop varieties of crops that are durably resistant to diseases, insects, and parasites. As a consequence, there will be less need for agrichemicals. New varieties will produce higher yields and improve income to the farmer, with lower impacts on the environment and improved food safety for consumers, even in the face of the impacts of climate change. Genomic sciences will make it possible to develop crops with elevated levels of nutrients that improve human health (e.g., vitamins, minerals, and antioxidants); foods will contain healthier oils, fewer allergens, and will contain less cancer-causing mycotoxins. Science will also produce healthier animal-derived foods (e.g., fish, pork) that use less feed and produce lower amounts of greenhouse gases and other pollutants than parent animals. Crop and noncrop plants will be enhanced using synthetic biology to develop plants that produce high levels of natural products that will replace chemicals produced by petroleum-based processes, creating a sustainable bioeconomy that enhances rural economics.

Unfortunately there are major challenges to realizing these and other opportunities. First, there is a severe shortage of financial support in Europe and the U.S. for genomic studies of plants and farm animals. Without fundamental discovery science and translation to innovation, food security and attendant economic growth will be slowed or not achieved. Second, the inability to translate genomic discoveries to products is slow and reliant on complex factors, including (i) an outdated regulatory process that stifles innovation, reduces the participation of entrepreneurs, favors large companies, and limits trade; (ii) a scientifically uninformed and agriculturally illiterate press that often discredits validated science by reporting equally on poor science in this field. Furthermore, scientific truths are not to be equated with philosophical or religious "truths."

Policy issues

- A substantial improvement in food security can only be achieved by accelerating research in the basic agricultural sciences, a goal that can achieved only with increased and sustainable funding, especially for the training of students and professionals.

- Many policies that regulate food and agriculture, including products derived from genomic sciences, are not guided by credible scientific understanding. Recently, many policy makers have become less familiar with agricultural practices (e.g., how seeds, crops, and animals are produced), which has made their decisions vulnerable to views often based on misinformation and mistruths expressed by vocal minorities. Policy decisions concerning food safety and security need to have a foundation in a scientifically based understanding of agriculture.
- Policies and regulation of seeds and foods developed in a GM-adopting country are generally not accepted by an importing country, in contrast to acceptance of nonadvanced foods and seeds. Food and agriculture products must be regulated independently of the method by which they are produced. Regulatory review of products should, as much as possible, be conducted in synchrony with the producing country; regulations must be harmonized based on sound scientific recommendations and be reviewed and revised periodically.
- Since the strong recommendations from scientific advisers and professional academies to use genomic sciences and agricultural biotechnology have generally not been endorsed by political leadership, many consumers have developed a negative view of GM foods. Political leaders, elected and appointed, need to endorse such sound science-based recommendations concerning the food and agriculture sector while acknowledging and facilitating the consumer's right to choose. Without such support, it will be difficult, if not impossible, to provide enough safe and nutritious foods for a growing population in the coming decades.

***** A policy position paper prepared for presentation at the conference on The Genomic Revolution, convened by the Institute on Science for Global Policy in cooperation with the Parliamentary Office of Science and Technology, on September 6, 2013, within the Houses of Parliament, London, U.K.***

Debate Summary

The following summary is based on notes recorded by the ISGP staff during the not-for-attribution debate of the policy position paper prepared by Dr. Roger Beachy (see above). Dr. Beachy initiated the debate with a 5-minute statement of his views and then actively engaged the conference participants, including other authors, throughout the remainder of the 60-minute period. This Debate Summary represents the ISGP's best effort to accurately capture the comments offered and questions posed by all participants, as well as those responses made by Dr. Beachy. Given the not-for-attribution format of the debate, the views comprising this summary do not necessarily represent the views of Dr. Beachy, as evidenced by his policy position paper. Rather, it is, and should be read as, an overview of the areas of agreement and disagreement that emerged from all those participating in the critical debate.

Debate conclusions

- Although genetic modification has a track record of safety that is supported by evidence from extensive research and clinical trials, the persistent public perceptions that GM products are dangerous remain widespread and limits public acceptance. Addressing public concerns about GM requires a coherent effort from relevant stakeholders (e.g., scientists, policymakers) and multifaceted strategies based on better communication about the balance of advantages and risks to accepting developing technologies (i.e., improved communications skills for scientists, well-informed, trusted spokespersons, effective collaborations with the media, engaging social and behavioral scientists in identifying cultural aspects of public acceptance).
- Although food, nutrition, and health are increasingly viewed as inextricably linked, the current gap in funding that separates research on health versus agriculture still exists. Increased investments in agricultural research would not only foster advances in agriculture itself, but also attract highly talented individuals to pursue these fields as researchers and teachers.
- While global harmonization of regulations begins with the 29 countries producing GM crops, it must engage the importing countries to accurately identify the relevant needs and challenges. What an international regulatory structure would look like remains to be determined, but such harmonization is more likely to succeed through multilateral efforts.

- The marketing of GM products in terms of the evidence-based benefits they provide can positively influence public perceptions and contribute to correcting erroneous perceptions of GM product risk and safety.

Current realities

Public perceptions (e.g., in the U.K.) of genetically modified organisms (GMOs) in general (i.e., regardless of animal, plant, or microbe modifications) remain negative and GMOs are viewed as dangerous to human health. Regardless of evidence generated from safety trials, these perceptions remain hard to change and result in tighter regulations that hinder further GMO development. This sentiment, coupled with distrust in multinational firms (e.g., conflicts of interest with regulators, actions taken in pursuit of profit without concern for public health, apathy towards the livelihoods of farmers, lack of transparency), has resulted in a lack of public acceptance for GMOs. Negative perceptions of GMOs have stemmed from media reports and the public's lack of understanding of science. However, it was observed that GM microbes were introduced to foods and received minimal public reaction, and therefore there has been some level of public acceptance.

Public perceptions of arrogance among scientists are a legitimate concern because those perceptions have essentially negated decades of evidence and data gathered on the safety of GM foods. Genetic modification is not an unsafe technology (i.e., in terms of the process or the final products produced) based on studies conducted for safety and efficacy. GM product failures are not a result of product safety (e.g., herbicide-resistant weeds) and many of the products are safer than their parent products as well as safer for the environment.

There is a lack of investment in fundamental research for food and agriculture focused on supporting food security, the bio-economy, and the farmer economy. These investments are less than 0.03% of the farm gate value (i.e., net value of the product when it leaves the farm). Support of science in an industry needs to be commensurate with the value of the industry, which is currently not occurring in certain economies that depend on agriculture exports (e.g., Canada's governmental body that funds competitive sciences removed food and agriculture from its primary areas of focus). Increased investment would not only lead to improvements in agriculture (e.g., in crop production), but would attract talent to the field's economic potential. Some locations (e.g., U.S. Midwest, Brazil) have demands from students (e.g., high schools, universities) for teaching and degrees that exceed current educational capabilities. There is a noticeable change in how farming is viewed: from an unprofitable, marginal activity to a lucrative enterprise, particularly in locations where agriculture is an important part of the economy (e.g., Brazil).

Currently, relevant stakeholders (e.g., universities, governments, institutes) have not created a coherent communication plan to the public. Universities have made efforts to improve communication through various initiatives (e.g., fundraising) and have reached out to the public to explain the value of technological advances (e.g., recombinant plants and their crops). However, there are inconsistent modes of operations and a clear lack of coordination. Improved coordination requires sustained commitments from the public and private sectors to collaborate. Ineffective communication also stems from a lack of understanding within the scientific community regarding the role that citizens' perceptions of the balance between risks and benefits, regardless of accuracy, play in public acceptance.

Opportunities and challenges

Although countries have different sets of regulatory requirements (e.g., food safety, environment), global harmonization of these requirements can build upon established practices demonstrated to be safe (e.g., plant breeding). While the relationship of the safety of food products and the environments in which they are grown and consumed are scientifically substantiated, the guidelines used to regulate these relationships, especially in view of rapidly emerging technological advances, need to remain flexible (e.g., for processes in plant breeding and mixing genomes for the purpose of producing safe crops). Such regulatory guidelines must be viewed from global perspectives if effective agreements are to be forged.

Currently, the 29 countries that produce GM crops do not have harmonization regarding regulations and guidelines, and there is an opportunity to begin with these countries to share information and develop guidelines. Food-exporting countries have the potential to take the lead in regulation while the importing countries can help to identify the challenges they face. Research is required to identify the primary issues, which can help create the structure of an appropriate oversight body. Multilateral entities may need to be involved to ensure global engagement and agreement, but to date, there are no agreements regarding the international regulatory structure.

The private sector takes a shorter-term view on the opportunities stemming from transgenic technology than the public sector despite the cost and rapid evolution of the technology from simple to more complex advances. Approximately half of the global expenditure of research efforts in the food and agricultural sectors is spent in the private sector. The current overlap of research between the private and public sectors, results in unnecessary duplication. Increased transparency and communication across both sectors, with a focus on collaborating across the relevant

processes and operational format, would result in mutual public and private sector benefits and reduce duplication.

Publicly communicating credible scientific results, together with the associated uncertainties, is a challenge best met by increased science education and improved understanding of the nature of risk and uncertainty. Unfortunately, some members of the public demand zero risks. Despite the overwhelming evidence that GM products are safe, the challenge remains in effectively communicating this information to the public through media of all types. Science education can combat ineffective communication throughout the public and help inform a new generation concerning the credible value in technological advances in food and agriculture. There is also much promise in efforts by journalists themselves to be better informed on scientific issues. (e.g., Mark Lynas, a British freelance writer on climate change and advocate of GM foods).

Improvements in science literacy have been facilitated by educational approaches involving experimental, hands-on methods that emphasize that science is integral to societal well-being. Such "systems approaches" towards scientific literacy foster new societal attitudes concerning science ranging from the relationships among different scientific disciplines to specific scientific terminologies. The approach is more general than any specific discipline and incorporates education and communication as tools toward science understanding. The systems approach provides opportunities to rectify a history of inadequate communication and highlights the basic transparency in scientific communities. Both can increase public understanding and result in more positive views of the beneficial influence of science and technology on individual lifestyles.

The failure in public acceptance of GMOs stemmed in part from a lack of understanding of the varying cultural interpretations of the sociology of food (e.g., France versus U.S.). To avoid a similar fate for new advances in biotechnology (e.g., synthetic biology, nanotechnology), it is important to engage social and behavioral scientists to provide insight into public perceptions that influence culturally specific viewpoints. Communication strategies cannot be the same for every society or for each new product. Messaging must be tailored for individual market centers.

Policy issues

Branding foods as organic has demonstrated the potential for increasing profit margins despite the absence of any scientific support of perceived benefits attributable to organic methods. It is evident that product marketability is not necessarily linked to evidence of product safety. Science-based decisions on product safety must be used to support rational marketing messages. If the products

are marketed in terms of accurately defined benefits or the reduction of risks as compared with existing products in the market, then new market opportunities can be opened (e.g., potatoes that do not use fungicides).

Since GMOs have not been challenged in certain instances (e.g., canola oil, canola meal in Europe and U.S., soy oil), there are existing avenues for market access. Marketing and/or describing products that contain, or not, certain ingredients or were grown with a specific technology can directly influence public perceptions. Examples include GM products sourced from a green technology and not sourced from a traditional chemical technology and thereby, resistant to devastating genetic disease. Product labeling must also communicate product benefits so that products are viewed positively (e.g., GM products labeled as eliminating risks such as bacillus thuringiensis [BT] crops not having organophosphates, product labeled as not having used atrazine resulting in less cancer-causing atrazine in the groundwater). The unwillingness to discuss benefits of technological advances in food and agriculture must be overcome, especially when the absence of credible information has unintended societal consequences.

The science community needs to actively publicly address incorrect perceptions that can be presented by the media and result in incorrect information permeating public opinions. As an example, on food safety issues, when journalists ask the wrong questions to define the safety of a specific food, scientists need to speak out, especially when there are allegations of nefarious uses of new technologies. If the science community does not take proactive steps toward communication, then the beneficial outcomes (e.g., green economy built on plants, renewable energy) of new technological advances (e.g., synthetic biology) for both growers and consumers will not be realized beyond a few products of high value.

Public acceptance of advances in genetic modification requires addressing the lack of trust in regulators and scientists. Distrust is perpetuated by the inability of scientists to effectively communicate science to the media and the public. There have been noticeable changes in communication within the U.S. and in Europe, albeit slower, because of regulations that may make it difficult for scientists to engage.

It is necessary for those in a position of influence and who have credibility beyond science (e.g., elected policymakers) to take the lead and understand the science behind different technological advances (e.g., personalized medicine) to justify their positions when communicating to relevant constituencies. Identifying trusted public advocates with media clout (e.g., Oprah, Dr. Oz) also can improve public acceptance. However, rather than trust in the source of a communication, public acceptance ideally needs to stem from a systematic social understanding of the science behind a product's safety. Mass media has an important role to play

describing the facts concerning product safety without resorting to sensational headlines.

There needs to be recognition and commitment to additional investment in science and in policies that make agriculture successful to human health benefit. Without investment, there is the risk of failing to meet global needs both environmentally and in terms of health and nutrition, which leads to societal instability and political unrest. There is also the need to address the rapid changes in climate and population that will require new technologies for societal sustainability. Coordination of efforts between the public and private sector must be made, and the public sector must invest in the underlying and foundational research to ensure an agricultural economy for the future.

The Genomic Revolution and Sustainable Management of Infectious Plant Disease: Aligning Policies with Objectives**

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Summary

Every year, persistent infectious agents and invertebrate pests cause multibillion dollar losses of crop yield and quality, as well as substantial ecological and landscape impacts (e.g., through tree disease). However, the "Genomic Revolution" is providing profound new insights into the diversity of organisms that exists in and on plants (above and below ground) as well as the sophisticated biology that plants deploy to discriminate among, and respond to, potential beneficial and detrimental invaders. This elevation of basic understanding is opening new opportunities for managing the risks posed by pests and diseases.

Plant disease management is most effective when several approaches are used to provide "integrated control": (i) use of disease-free seed or planting material (including quarantine); (ii) exploitation of genetic resistance; (iii) creation of physical, chemical, or biological environments hostile to pathogen development (e.g., use of fungicides). All three components are influenced by genomic technologies, as well as by policy and regulation. This prompts an examination of where science, policy, and societal interests are not aligned. I suggest four particular areas: (1) exploitation of plant genetic biodiversity and intellectual property protection, (2) regulation of "novel" products (e.g., crop varieties expressing new characteristics) as distinct from technology enabling their development (e.g., transgenesis/genetic modification), (3) discrimination between invasive aliens (transboundary immigrants) and endemic variants (e.g., virulent mutant of a long-established resident), and (4) the "market failure" of inadequate investment in "minor" or locally adapted crops of nutritional importance compared with globally traded staple crops.

Current realities

Plant pathogens (e.g., fungi, oomycetes, bacteria, viruses, and viroids) are transmitted between plants over short or long distances in four ways: (1) in or on seed, other types of propagating material, or living products (e.g., fruits or tubers);

(2) contaminated soil or water; (3) air-borne propagules (such as fungal spores); and (4) animal vectors (e.g., insects and nematode worms). For brevity, the focus here is on infectious diseases of food crops; all that follows could equally apply to invertebrate pests and to nonedible plants including forest and ornamental trees. This paper also concerns the tools and technologies used to reduce the risk and magnitude of crop loss due to diseases. In particular, the science of genomics will increasingly impact on options for the detection, discrimination, and practical management of pathogens in crops, including exploitation of the plant's immune system and the diverse microbial biota that exist in association with plants. Almost all tools and technologies used to manage plant diseases are subject in some way to regulation and are influenced by policy.

Although accurate estimates are difficult to obtain, global crop losses caused by pests, diseases, and weeds probably exceed 40% of the total market. Verifiable estimates of global annual crop yield and quality loss due to crop diseases alone are at least 10% to 15% — a value exceeding $75 billion. The total market for crop protection chemicals is approximately $38 billion, with fungicides accounting for approximately $10 billion. Losses caused by pests and diseases are not simply economic; human lives and livelihoods depend on predictable and reliable crop yields. Disease equates directly to wasteful, inefficient resource use (water, energy, fertilizer, land) and leads to greater greenhouse gas (GHG) emissions per unit of production.

The application of genomic science and technology (as well as policies delivering appropriately designed and proportionate regulation) can help to alleviate four constraints on meeting the above challenge. (1) Evolution is a powerful force working against sustainable disease control. Widespread use of a crop-protection chemical or deployment of a particularly effective resistance gene will select for pathogen variants that are insensitive to the control regime. As a result, efficacy will be eroded (similar to the development of antibiotic resistance). (2) New diseases and novel variants of well-recognized pathogens are frequently emerging in new regions and crops. A combination of increased global movement of people and plant products, as well as climate change, is likely the cause. (3) Societal opposition to the purported "chemical dependency" of agriculture and the returns on investment (ROI) of new chemistry are less certain, partly due to the costs associated with stringent regulatory regimes and inadequate information about potential biochemical targets for intervention. At the same time, the use of biotechnology (a substitute technology) is also being constrained by societal pressure and regulation. (4) While markets for staple crops, grown on large areas and traded internationally (e.g., maize and soy), may provide a sufficient ROI for large corporations using either genetic or chemical

innovations, this is not the case for the vast majority of regionally adapted minor or "orphan" crops (e.g., fruits, tubers, and vegetables). These orphan crops are of fundamental importance in provision of a varied and nutritionally balanced diet. In summary, reducing diversity in options for control, increasing disease pressure, high costs of market entry, and uncertain ROI are leading to a focus on limited crops and disease targets by a small number of large corporations. This is not the recipe for increasing resilience to the threat of crop diseases.

Scientific opportunities and challenges

A laudable global objective is for growers to have access to an affordable set of tools enabling them to exercise reliable integrated control of the whole gamut of diseases that threaten their crops. Advances in crop and pathogen genomics bring this goal closer.

Pathogen-free planting material is the starting point, particularly for perennial crops and diseases caused by viruses and bacteria. Genomic technologies now provide the prospect of detecting, identifying, and determining the source of contaminant pathogens carried in or on seeds and other propagating material at vanishingly low levels. Proportionate systems of surveillance can be founded on sound assessments of risk and benefit and implemented by applying innovative detection technologies such that diseased material is rejected and pathogen introduction is avoided. Sole reliance on a single chemically active ingredient or a single gene for resistance does not constitute a stable, resilient control strategy. Directional evolutionary change in a pathogen population, leading to control failure, is best countered by creating system diversity. Genomic science and technology provides access to this diversity. Knowledge of plants' immune systems now provides the ability to mine genetic diversity and to identify, select, or engineer the gene sequences that will most likely provide protection against those pathogen variants to which crops will be exposed. To do this requires detailed knowledge of pathogen diversity and specifically, the sequences of genes that are essential for pathogenicity. Elevated knowledge of pathogen genomics is simultaneously enabling the identification of molecular targets for known and new chemicals with the prospect of designing a combination of molecules where evolution toward resistance would come at a debilitating or lethal cost. Genomic science is thus improving access to required chemical and genetic diversity.

In addition, how can tools and technologies be provided not just to address the most important diseases of major global crops (e.g., rice blast, cereal rusts, potato blight), but also the myriad diseases causing losses in dozens of minor crops grown for regional markets or by subsistence farmers? There is a "market failure" here,

where the costs associated with investment in the necessary innovative technologies cannot provide a return because of the low economic value attributable to each of hundreds of crop and pathogen combinations. Solutions will lie in exploiting the diversity that genomic science is demonstrating as important in providing "natural" suppression of disease. Such innovations may lead to nonsaleable novel practices, promoted as public goods, as distinct from innovative products marketed for profit.

Policy issues

There are four interrelated areas of policy where applications of genomic science, reducing losses from crop disease, and the derivation of public benefit should be more closely aligned:

- Advances in genomics are revealing the enormous potential for provision of durable crop resistance to diseases through the exploitation of plant genetic biodiversity. However, this potential is not being realized because when international treaties on biodiversity and utilization of germplasm, the patenting of crop varieties, and the weak "market pull" for most crop and disease combinations are factored together, their effects are inhibitory. *National governments, working with the United Nations, must encourage the unfettered and intellectual property (IP)-free exploitation and utilization of plant germplasm for programs of both publicly and commercially funded crop genetic improvement. There should be no patent protection of crop varieties which, without exception, need to be freely available for use as parents by others.* Returns on commercial or public investment can be provided by royalties on registered varieties under internationally agreed arrangements for "Plant Breeders' Rights."
- *Multinational governance bodies need to encourage national governments to adopt policies that focus public resources on the genetic improvement of "minor" (but nutritionally important) crops* where commercial investment is low due to "market failure." National governments, by partnering and other inducements, can encourage commercial investment in crops where market returns make this an attractive and viable venture.
- Crop improvement for disease resistance has societal benefits that have been delivered through dozens of crops for over a century. Genomic science and technology provides the opportunity to make this process more effective and efficient, but it is being impeded in many countries by disproportionate and unscientific regulation of certain biotechnologies. *National governments, with the U.N., must work toward international agreements whereby crop*

varieties expressing well-established beneficial traits (such as disease resistance) are deregulated regardless of the technology deployed in their development. In the case of a "novel," previously unavailable trait, the regulatory regime must focus on the impact of its use rather than the (bio)technology enabling its development.

- In the context of disease surveillance and implementation of quarantine arrangements for movement of plant materials, genomic science and technology is providing new tools and insights. *National governments, working with the U.N., need to reappraise international trade agreements that reference named plant pathogens and implement surveillance (with associated regulation) that is proportionately based on realistic, science-based analyses.* Detection of potentially damaging variants of long-established and resident organisms that express novel virulence characteristics can represent a greater (and more certain) risk than previously undetected trans-boundary immigrants.

***** A policy position paper prepared for presentation at the conference on The Genomic Revolution, convened by the Institute on Science for Global Policy in cooperation with the Parliamentary Office of Science and Technology, on September 6, 2013, within the Houses of Parliament, London, U.K.***

Debate Summary

The following summary is based on notes recorded by the ISGP staff during the not-for-attribution debate of the policy position paper prepared by Professor Ian Crute (see above). Prof. Crute initiated the debate with a 5-minute statement of his views and then actively engaged the conference participants, including other authors, throughout the remainder of the 60-minute period. This Debate Summary represents the ISGP's best effort to accurately capture the comments offered and questions posed by all participants, as well as those responses made by Prof. Crute. Given the not-for-attribution format of the debate, the views comprising this summary do not necessarily represent the views of Prof. Crute, as evidenced by his policy position paper. Rather, it is, and should be read as, an overview of the areas of agreement and disagreement that emerged from all those participating in the critical debate.

Debate conclusions

- Since food security is widely acknowledged as an immediate and urgent worldwide problem and no global consensus regarding solutions currently exist, it is necessary to rapidly create a coordinated, multiregional response to characterize and address the foreseeable threats to worldwide food security.
- Crop improvement is dependent on understanding the genetic composition of both crops and disease pathogens. Currently, genetic modification of the (food) crop itself may be perceived as potentially harmful to humans, while modification of the cause of the disease may be perceived as beneficial.
- There is a risk/benefit balance when any new technology, such as genetics and genomics, becomes a replacement for an established technology, such as chemical pesticides. However, in some instances, the precautionary principle has been used in a perverse way, in that the principle has been used to justify the removal of certain pesticides without considering the consequential risks of such removal.
- While strong protections for intellectual property rights (IPRs) generally promote innovation, the advances from such innovations must not be withheld from less-affluent countries that require crop-improvement technologies to advance food security. There is an urgent need to resolve issues concerning IPRs and technologies that improve crop quality and yield for less-affluent countries.
- A burdensome regulatory framework acts as a barrier to entry to smaller players in crop innovation and other fields. Opponents of genetically modified (GM) technologies are partly responsible for the burdensome regulatory morass currently in place.

Current realities

Using a simple staple crop (e.g., potatoes) may be an effective method to communicate complex messages and issues concerning crop disease. There are hybrid potatoes that cross some European potatoes with a strain from Egypt to create a blight-resistant crop. However, it is also simpler and more direct to obtain the same end result through genetic manipulation. It was agreed that one can produce a potato with good characteristics (e.g., high yield, disease resistance) through several means. Hybridization with wild species takes 30 to 40 years, while direct gene transfer (i.e., GM methods) is a much more rapid process. Both processes result in the same

outcome, which is a genetically modified crop with improved characteristics. Thus, it is the trait or the actual outcome that is important to regulate. The development of disease-resistant crops is a classic example of technology neutrality (hybridization versus direct gene manipulation), which offers a strong argument to regulate the end product, and not the process technology used to obtain the improvements.

There is a lack of preventive or anticipatory strategies to combat and control plant diseases. The asymmetry in certain regions of the world in relation to population growth and food production (i.e., population growing more rapidly than food production capability) will increase movement of plants, food, and products globally. This increased movement will result in a wider and more rapid spread of crop diseases. While some policy makers recognize this trend, many countries still are primarily in a reactive, rather than proactive, mode. There is an important and urgent need to create anticipatory or preventive strategies to pests and diseases. There was concurrence that it is extremely important to increase surveillance and anticipation activities. The case of a disease that exists in China, but not yet in Brazil, was highlighted as an example of a disease which is known, and that can be monitored for geographic movement. Another more subtle but equally important issue is the genetic variance of known diseases. Examples of a wheat stem rust disease (e.g., the spread of the Ug99 from Africa) and the ash die back disease in the United Kingdom were noted as such genetic variations. A much more sophisticated approach from the point of view of policy and regulation will be necessary to address such disease variations.

Genetic modification can be applied to the crop itself and/or the disease pathogens. These two approaches seem to have quite different public perceptions. Modification of the (food) crop itself may be perceived as potentially harmful to humans, while modification of the cause of the disease may be perceived as beneficial. This view was not contested, and the importance of understanding the genome of the crop and its associated pathogens was highlighted. There is an urgent need for more effort to understand the genomics of the "enemy." Amplification of innate immunity of a crop against a specific pathogen is a high-value endeavor. Only by understanding the genomic interplay between the crop and the pathogen can such approaches be pursued.

Current examples of crop improvement applications of genetic modification and synthetic biology help policy makers and the general public understand and better accept such emerging technologies. One such example is the Bacillus Thuringiensis gene, which provides resistance to Lepidoptera insects across a wide range of crops. This technology has been spectacularly successful globally, both directly to the crops, but also ecologically. The reduction in insecticide use is a

direct advantage, but it has also resulted in fewer beneficial insects being killed by insecticides, which is a clear environmental benefit from the introduction and dissemination of this technology.

A question was raised as to whether the food security issue is an immediate and urgent worldwide problem (an "asteroid" issue, demanding a coordinated and urgent response). In the Forsythe Report, climate change was characterized as extremely important, and food security and natural resource issues are currently being dramatically impacted by climate change. Throughout the report, the conclusion was that the food system is broken. It was also acknowledged that a global consensus on some of these issues is still decades away.

Scientific opportunities and challenges

Risks and benefits must be weighed when new technologies (e.g., genetics and genomics) replace an established technology, such as chemical pesticides. Scientists have failed to demonstrate this balance of risk when those who object to pesticide use also object to their substitution with genomics technologies. An objective presentation of the required balance between the risk and benefits of the competing technologies should lead policy makers to understanding that risks may be mitigated through novel approaches that maintain the benefits. A broader view of the problems and solutions would be helpful. The analogy of tools in the tool box, when it comes to pest disease control in agriculture, may be a useful one. There will never be a single solution, rather a mix of genetics, prevention/avoidance (through surveillance), and chemistry. Usually, when disease control fails, it is more a matter of considering only one aspect or approach.

Crop diseases can be a threat to worldwide food security. Known diseases that attack wheat, rice and soybeans could become significant threats in the next decade. However, given the economic impact of these major crops, there is likely to be sufficient resources to combat and control any such outbreaks. Another concern is the impact of diseases on smaller "orphan" crops that are extremely important for local nutrition, but have little or no commercial impact. Diseases that attack orphan crops also require attention from governments. Another vulnerability to food security is the fact that the world has too few bread baskets. Natural disasters or extreme weather conditions in one or two important agricultural regions could result in serious and widespread food shortages worldwide.

Some technology advances are diminishing the protection that Plant Breeder Rights (PBRs) have offered to seed producers. New molecular tools allow other breeders to introduce a new trait into their crops much faster than was possible historically.

One of the most important environmental benefits of crop improvement, both in yields and disease resistance, is the impact on land. If food can be produced on the smallest acreage of land necessary, then there is more land available to maintain forests, grasslands, and other habitats that support biodiversity. Thus, highly productive and intensive agriculture is an environmentally beneficial solution. Land use is a significant policy area regarding agriculture and environmental impact of agriculture.

Plant diversity is a largely untapped resource that may provide solutions to climactic and other environmental challenges. Current orphan crops may be appropriate as a wider, global food source. Also, in the same way that scientists prospect for microorganisms for characteristics to exploit, it is possible to prospect in terms of plant biodiversity and characteristics (e.g., medical, nutritional, industrial) that may be useful in addressing potential future environmental challenges.

Policy issues

The suggestion IPRs relating to crop improvement technology should not be owned ("IP-free" concept) was discussed and clarified. Questions were raised concerning compensation for investors in new technologies, the geographic scope of the IP-free concept, the technology breadth of the concept, and ownership issues. It was noted that in plant breeding in certain regions, there is a method of recovering royalties termed PBRs. These PBRs allow a breeder of a new variety to recover royalty through seed sales, without impeding the use of that variety as a parent in subsequent breeding. The PBR concept is contrasted by the patenting of a plant variety, which may actually impede the continued genetic improvement of that variety. It was also suggested that some defensive patenting of varieties (without significant improvements) sometimes takes place. The decision around IPRs will vary case-by-case, depending on goals and objectives of a certain technology. There will be circumstances when traditional IP ownership is absolutely the right thing to do, notably in some of the crops that do require significant commercial investment. However, in other circumstances, an IP-free approach may spur and propagate innovation.

The issue of biodiversity and IP was raised. The regulation or treaty concerning the exploitation of biodiversity is built on the premise that the biodiversity is owned from whence it is taken. It was argued that this approach is actually not helpful, primarily because the source of biodiversity relating to crop improvement is generally not the best region for scientific exploitation of such improvements. Thus, the suggestion of an IP-free environment would be *quid pro quo*, allowing free access

to biodiversity to explore and to scientifically exploit and in return receiving free access to the fruits of that investment for the benefit of all regions.

Concerning IP, there are ways to move forward in a mutually beneficial process for scientists, industry and farmers. As an example, cocoa is very important to many companies as a raw material. Also, there are 3 million cocoa farmers worldwide. A public-private partnership was formed to accelerate the identification and mapping of the cocoa genome. Ownership of the genomic information was not an issue, as the intention was to make that freely available to researchers. Over the last decade, this genomic information has greatly accelerated cocoa research.

Regulation of technology processes, rather than end products, often leads to the unintended consequence of the emergence of new technologies by which the genetics of plants can be changed without hybridization. It appears that the motivation for such approaches is actually to avoid the overregulation of genetic modification. Yet the outcome is the same.It is a reasonable approach to regulate at the technology level in certain circumstances, such as engineering a plant to create a long chain of fatty acids. Since plants had never produced such compounds before, it would not be unreasonable to regulate at the technology level. There was concurrence that blanket regulation at the technology level is not necessary and that it stimulates researchers to develop new technologies to avoid the technology being regulated.

Strong IPR protection generally promotes and enables innovation. However, policy makers and the general public often do not understand or appreciate this relationship relative to food and crops. When dealing with global food security, IPRs must not impede the logical dissemination of crop improvements to less-wealthy regions. There was consensus that issues regarding crop improvement IPRs are resolvable and need more discussion than they have received in the past.

A burdensome regulatory framework acts as a barrier to entry to smaller players in crop innovation and other related fields, resulting in a situation in which only organizations with significant resources can meet the regulatory challenges and actually bring products to the market. It was argued that, relating to small, orphan crops, there are technologies that would be beneficial, but may never be applied due to regulatory hurdles. Opponents of GM technologies are partly responsible for the burdensome regulatory morass.

Integrated versus nonintegrated policy was discussed briefly. In the European Union, a classic example of nonintegrated policy is the Directorate-General (DG) in Europe that monitors environmental issues. The DG makes policy on regulating agricultural chemicals based solely on hazard without any assessment of risk. There is also a DG associated with agriculture that promotes the requirement for increased food productivity and more efficient use of land. These two regulatory bodies are

disconnected. It was argued that, in this example, the precautionary principle is used in a perverse way, in that the principle was used to justify removal of certain pesticides without considering the risk of such removal.

The Emerging Landscape of Medicine and Health Care**

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Summary

Advances in genomic and systems technologies have led to the emergence of personalized medicine as a paradigm shift in health care. Rapid sequencing of DNA and proteomes has facilitated a systems approach to medicine that allows the identification of the multiple variables contributing to health and disease. Technologies under development will allow more rapid diagnosis of diseases at increasingly granular and individual levels, which will in turn provide opportunities for more personalized, effective, and less expensive treatments. The combination of these factors has created what has been termed P4 medicine — predictive, preventive, personalized, and participatory. If society and policy makers are able to fully capitalize on the opportunities offered by P4 medicine, the quality of health care can be improved, costs can be reduced, and innovation will be catalyzed to fuel wellness and health care for the future.

Current realities

The landscape of medicine has changed profoundly in the past 10 years with the emergence of personalized medicine. Over the 40-some years of my career, I have participated in four paradigm changes in the biological sciences that have led to profound changes in medicine and biology.

First, I brought engineering to biology by inventing five instruments that allowed one to analyze and synthesize the fundamental molecules of life: protein and DNA. These advances heralded the revolution of "big data" that is so essential to personalized medicine. Second, I was one of the leaders of the human genome project, due to my invention of the automated DNA sequencer, which enabled genome (DNA) sequencing. The genome project both provided a complete parts list of all human genes (necessary for systems medicine) and opened the possibility of personalized medicine by enabling the analysis of the genome sequences of individual patients and their cancers.

Third, I founded the Institute for Systems Biology, the first institute to use

systems or global approaches for studying biological complexity. To illustrate, consider how one might understand how a radio converts electromagnetic waves into sound waves. One must not only identify all the parts in a radio and understand what they do individually (as biology has done for the past 40 years with individual genes and proteins), but must then assemble these parts together into their circuits and study, individually and collectively, how the circuits enable the conversion of radio to sound waves. So it is also with living organisms, which have circuits or networks that manage biological information whose components, circuits, and dynamics need to be described to decipher biological complexity.

Finally, I was one of the early advocates of taking a systems approach to disease, otherwise known as systems medicine. There are three central features of systems medicine. First, disease arises from two types of biological information: mistakes in the digital genome and pathogenic environmental signals (such as infectious organisms). The challenge is to be able to identify and assess the relative contributions of both of these types of information to disease. Second, in five to 10 years, each patient will be surrounded by a virtual data cloud of billions of data points, and the analytic tools will exist to reduce this enormous data dimensionality to simple hypotheses about optimizing wellness and minimizing disease for each individual patient. These individual data clouds will enable the assessment of both the genomic and environmental contributions to disease. Finally, each patient has a biological "network of networks," which are biological networks that operate at many different levels of information — molecular, cellular, organ, and social — each of which are seamlessly integrated in each patient. In disease, these networks become "disease-perturbed" and alter the information they generate. A systems approach permits us to identify this altered information that, in turn, explains disease mechanisms and provides new insights into diagnosis and therapy.

Scientific opportunities and challenges

Systems medicine has reached a tipping point and is transforming the practice of medicine through a number of advances.

Revolutionizing DNA diagnostics. New genetic approaches, such as the sequencing of the genomes of families, are enabling physicians to more readily identify disease and wellness genes. These approaches have been used to identify interesting disease genes for a variety of neurodegenerative diseases, bipolar disease, and some metabolic diseases. The human genome sequence currently has about 300 "actionable gene variants" — variants that, if identified, can lead to behaviors to improve the health of the individual. For example, in the case of a person who developed osteoporosis in his late 30s, genetic analyses found he had a defective

calcium transporter, and as a result he was able to reverse the disease by taking 20 times the normal amount of calcium. Without being able to act on this information, he might have spent the rest of his life in a wheelchair. As the numbers of actionable genes increases, a person's genome sequence will be able to be checked each year against new actionable variants — an investment in health that will continue the rest of the person's life. In addition, there are 70 mutant genes that block patients from responding effectively to certain drugs, so knowing whether a patient has one of these genes before drug treatment is very important. Certain individuals cannot effectively utilize common drugs because of genetic defects.

Revolutionizing blood diagnostics. Systems approaches have made blood a window into health and disease by pioneering procedures to identify blood biomarkers that can diagnose virtually any disease. For example, biomarker panels can distinguish benign from cancerous lung nodules. This information could save the American health care system billions of dollars a year by avoiding surgical procedures on the 95% of patients with benign nodules, and bring "peace of mind" to these patients. Individuals having posttraumatic stress disorder (PTSD) can be distinguished from those who do not. These new blood biomarkers will be able to (i) distinguish sick from normal patients, (ii) detect disease early, (iii) follow the progression of disease (future treatments will, in part, be determined by the stage of the disease), and (iv) follow the response to therapy. The systems strategies for blood diagnostics can easily be extended to most other diseases. Each of these diagnostic opportunities will reduce the cost of health care by making disease management more effective.

Stratification of disease into different subtypes. This is important because each disease subtype will require a unique therapy and will have a unique prognosis. Diseases that have been stratified include several types of cancer, such as breast cancer. With the stratification of diseases, optimum impedance matches (i.e., most potent response) can be identified between the subtype of disease and effective drugs.

More effective targeted use of drugs. Drugs can be targeted to treat patients' individual cancers. By sequencing the genome of cancers, the specific genes that are mutated can be determined and an appropriate drug that will be effective for these mutations can be identified. This approach can be effective for some melanomas, colon cancers, breast cancers and many other cancer types.

Invent cheaper and more effective drugs. Knowledge of disease-perturbed biological networks can be used to select drug targets that will optimize the ability to re-engineer these networks back to normal. This is a novel and powerful strategy for selected drug targets. Drug companies are effective at developing drugs, but not at choosing drug targets. Thus, the marriage of the systems approach to identifying

drug targets with the pharmaceutical industry's ability to make drugs will lead to drugs that are far less expensive to develop.

Focus on optimizing wellness for each individual. Increasingly, there will be a focus on optimizing wellness for each individual, rather than just worrying about disease. Once again, this behavior will lead to enormous savings for the health care system.

The convergence of systems medicine, big data and its analytics, and patient-activated social networks has led to a new type of medicine termed P4 medicine — predictive, preventive, personalized, and participatory. The predictive and preventive aspects have been described above. Personalized indicates that each patient is genetically different from other people and hence must act as his or her own control for analyzing personalized data clouds. Participatory suggests that patients will become more involved in optimizing their own health and thus in minimizing disease. Such patient-activated social networks will be one of the major driving forces in bringing physicians and the health care system to accept systems medicine and P4 medicine.

Policy issues

P4 medicine will transform health care by improving the quality of care, strikingly decreasing costs, and promoting innovation to create the companies fueling wellness and health care for the future. As a result, there are a number of implications of P4 medicine for society.

- P4 medicine will reduce the ever-escalating costs of health care to such an extent that advanced health care can be exported to the developing world, thus generating the possibility of a democratization of health care that was inconceivable even five years ago. There should be substantial societal investments in P4 medicine to speed up this process. Moreover, facilitating wellness-relevant, patient-activated social networks will facilitate the acceptance of P4 medicine in the face of the conservative nature of health care systems and practitioners.

- P4 medicine is leading to a digitization of medicine that will reduce enormously the cost of personalized data clouds. One can see this with devices that permit "quantified self" measurements (e.g., sleep, weight, and fitness measurements). Just as the digitization of communications and information technologies led to enormous reductions in costs in these sectors, so too will the digitization of medicine lead to a reduction in the

cost of health care. Economic incentives will be needed to facilitate this digitization of medicine.

- Each industrial sector of the health care system will have to rethink its business plans according to the challenges and opportunities of P4 medicine. Some companies will be unable to accommodate the new imperatives of P4 medicine, thus opening up exciting new space for the creation of new companies that are structured to take advantage of the opportunities of P4 medicine. P4 medicine will facilitate health care innovation in conducive policy environments.

- P4 medicine will create significant wealth for the countries that adopt it early. For example, the market capitalization of the wellness industry will potentially far exceed that of the current health care industry within 10 to 15 years. Thus, we now have the opportunity to create the companies that will fuel a major economic sector of future industry. The question of which policies will best facilitate this process will be a key one for policy makers to address.

- P4 medicine will advance most effectively by making personalized data clouds available for analysis by qualified scientists to generate the medical advances that will transform the health of future generations. Policies will be required to balance this imperative with issues of security, privacy, and ethics.

***** A policy position paper prepared for presentation at the conference on The Genomic Revolution, convened by the Institute on Science for Global Policy, in cooperation with the Parliamentary Office of Science and Technology, on September 6, 2013, within the Houses of Parliament, London, U.K.***

Debate Summary

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Debate conclusions

- A paradigm shift, based on a "systems approach" to understanding the complexity of disease, has paved the way for the multidimensional recording and analysis of health data termed P4 medicine (i.e., predictive, preventative, personalized and participatory). A systems approach fosters a targeted and simplified method for diagnosis and therapy that can considerably reduce health care cost through the analysis of biological networks and identifying effective drugs for specific patients. While the net saving remains to be established, the ability of P4 medicine to digitize medical data is expected to facilitate the export of health care to less-affluent countries at lower costs.
- While a systems approach to medicine facilitates data sharing, it also raises issues concerning the privacy and security of these data. Concerns related to the use of digitized health data for genetic discrimination (e.g., profiling, health insurance) needs to be addressed by enacting protective laws and/or mechanisms to insure data protection (e.g., using trusted third parties). Legal constraints to prevent data exploitation also help to improve the societal commitments to provide personal health data.
- Although there is credible scientific evidence closely linking food, nutrition, and health, the data needed to define guidelines regarding what should be eaten to maintain nutrition is lacking. A systems approach to define nutritious food has the potential to generate the relevant data required for analysis. While there may be resistance from traditional and established

government-funding bodies, which often do not support these studies, other funding opportunities are available from philanthropic organizations and multinational stakeholders.

- Since comprehensive health data can for the first time be analyzed through powerful tools (e.g., cloud storage) designed to provide information for predictive medicine, there are opportunities to transform health care for future generations if patients consider providing personal health data as an obligation. Improved public communication focused on the benefits of genome sequencing is required. The effectiveness of such communication must involve positive, consistent language addressing disease causes and views that reflect different social networks, locations, and cultures.

Current realities

The participatory nature of P4 medicine does not necessarily require a scientifically literate population in its beginning stages. These stages can be compared with social networks that began from self monitoring (e.g., exercise, blood pressure, respiration), which did not necessarily require specialized knowledge. These networks allow for crowd sourcing and developing an understanding as to how to best optimize the data gathered. These networks have also, in some instances, driven medical practices to change and improve.

Gene sequencing is rapidly advancing (i.e., it is predicted that the whole human genome will be sequenced in 15 minutes for $100 in 5 to 8 years). Understanding and measuring epigenetic changes (e.g., direct chemical modification, histones) in DNA modifications is also predicted to soon be understood on a global scale. Such a systems approach provides new ways to integrate and model data characterized by the analysis of DNA, proteins, cellular composition, organ health, as well as individual social networks. Already there have been successes in complex deconvolutions, reassembly, and creation of models, which have given deeper insight into disease mechanisms that are predictive in terms of the histopathology that follows them. However, it was argued that there is a danger of oversimplifying and overinvesting in further technological advances based on the expectation that they can provide additional solutions when there is already a plethora of data available to be analyzed and interpreted.

Over the next 20 years, the Institute for Systems Biology (ISB) has committed to a longitudinal study designed to frequently measure and analyze the complete genome sequence of 100,000 healthy participants. This study will aggregate patients with similar genetic and environmental factors into cohesive groups. Unlike current clinical data trials, which do not account for individual patient genetics

and environments, the ISB data can be used to identify tailored treatments (e.g., using specific nutrients and minerals) intended to optimize health outcomes. The accumulation of the data into a database also will allow for future analysis (e.g., for spinoff companies, for understanding wellness and disease, for matrices for wellness optimization). The participants in the IBS study will be drawn from diverse societal backgrounds in efforts to understand the individual impact of their respective environments.

The systems approach to lung diagnostics has resulted in $3.5 billion in cost savings. This approach can be applied to any disease, but it remains to be established the extent a systems approach will result in an overall net savings in health care costs. Additionally, while P4 medicine may reduce health care costs, new or additional social costs may occur (e.g., increased cost of Social Security in the United States linked to increased longevity of life), which has been arguably described as a systems failure problem in the purview of social science and not medical science.

Opportunities and challenges

The facilitation of data sharing focused on understanding the overall value of health care data beyond the genomic information itself must include a broad range of patient information. Data sharing across companies and among private researchers, of course, raises issues regarding patient confidentiality. The consequences of the perceived inappropriate use of patient data are serious breaches in privacy that must be challenged if public distrust, similar to that associated with the use of genetically modified food (GMOs), is to be avoided.

P4 medicine promises to democratize health care information to a level previously inconceivable and potentially lower the associated costs to foster improved exposure to health care options to less-affluent countries. However, there is concern that targeted treatments will cost more to develop than conventional therapies. Relevant examples once believed unfathomable (e.g., digitalization of communications so that a woman in rural India can make a living with her cell phone) suggests a similar outcome for the digitization of health care information and the opportunities stemming from lower costs.

The ability to stratify disease into its different types and the digitalization of medical information has the potential to prove transformational. Further, the ability to use these system approaches to identify drug targets can change the dimensionality of the cost of drugs. Certain areas in medicine (e.g., cancer, induced pluripotent stem [IPS] cells) already have begun to realize the benefits of P4 medicine. Opportunities to improve access to individual wellness are also feasible through development of a matrix that can measure dynamics and optimize accordingly for the individual.

Finally, there has already been much progress in understanding aging (e.g., 18 genomes have been sequenced for individuals 115 years old and older) and efforts continue to explore the purification of genes that optimize aging traits with the potential to minimize those that might shorten life.

Genome samples must be obtained from throughout the world population if the resulting data are to be globally applied and not solely used to benefit a small sample of people who can afford to have their DNA analyzed. Obviously, the challenges associated with obtaining DNA analyses on a world scale are considerable.

Integration of food, nutrition, and health issues can help shift the health care paradigm from reactive to preventive. One example is the development of food with better nutritional density and with new functionalities that provide better preventive health care. While existing data on nutrition are poor, P4 medicine offers the potential to provide data through patient-activated social networks toward efforts at preventative wellness. Specifically, on family networks that characterize nutritional health in enough detail to encourage compliance with nutritional decisions that improve health within the network. However, social networks might not identify adverse individual reactions to certain nutritional regimens (i.e., in the same way there are individual side effects with drugs) and, therefore, there is a role for self-diagnostics.

A paradigm shift in public funding of new programs is a critical challenge in modifying health care objectives toward preventive medicine and wellness. Government health care programs (e.g., National Institutes of Health [NIH]) currently fund existing infrastructures and restrict scientific funding to new types of programs. Therefore, different sources beyond public funding (e.g., philanthropic) will be required to bring reality to the expectation that P4 medicine can be established (e.g., the 100,000 participant longitudinal study by IBS).

Policy issues

It is crucial to convince the public that patient data will not be identified with individuals, but rather that encryption mechanisms are in place that will ensure the anonymity of these data. The public must be accurately reassured that the benefits of data sharing with respect to significant improvements in human health justify the potential risks associated with any loss of anonymity. Semantics must be carefully considered in terms of perception related to certain words (e.g., cloud storage) which may be misconstrued by the public as open and accessible. The real concern related to identity and privacy is to insure against genetic discrimination (e.g., profiling by insurance companies, employers, families, governments) by insuring that appropriate and protective laws and constraints are put in place.

Uniform Institutional Review Boards (IRBs) are needed that allow qualified personal to have unrestricted access to medical data, which is a departure from the current restrictive and inconsistent IRBs.

While discovery research is encouraged, government regulations (e.g., future proof of safety) hinder the development and implementation of innovative products and their appearance in the marketplace. Since the cost of creating and marketing an effective product is enormous (e.g., pharmaceutical companies spend half a billion dollars investing in analyzing genomes for vaccine targets for immunization), existing governmental regulations need to be continually reevaluated.

Systems approaches are predicted to reduce the cost of discovering and developing new drugs (e.g., studies can target how to induce cellular immunity effectively for the development of vaccines), and initial funding sources (e.g., federal funding, international strategic partnerships, collaborations with industry, venture capital) are successfully obtained by aggressively following through on a compelling or innovative idea. Further success will require more funding for professional training.

To realize improved societal wellness from genome sequencing, it is imperative to frame genome sequencing as positive and communicate benefits to the public. The driver for having one's genome sequenced is that currently there are 300 actionable gene variants known that, if identified, can dramatically improve health (e.g., genetic analysis can result in identifying a defect in calcium transporter for which a targeted and specialized treatment has the potential to reverse severe and debilitating osteoporosis). Some of the 300 variants are rare, but not all; and as more variants are found, existing genome sequences can be checked for them. While genome sequencing can be described as an investment in optimizing wellness for life, it must be made clear that it is optional. Those who fear receiving bad news from their genetic analysis must be reassured that knowledge is useful particularly in regards to being able to act quickly if and when relevant treatment surfaces.

Caucus statement

This summary was prepared by the ISGP from remarks made by Prof. the Baroness Ilora Finlay of Llandaff in her role as a Caucus Leader

- In considering issues related to the Genomic Revolution, it is important to take a global perspective. Specifically, such a perspective must consider what policies would benefit less-wealthy countries, as well as considering the multiple challenges reflecting the perspectives and interests of more-wealthy countries. In a broad sense, improving and maintaining global stability (i.e., allowing people to live peacefully together) requires the narrowing of the current social divides that separate poor and wealthy people. Increasing economic, political, and general societal equality worldwide can be aided through wider access to technologies in agriculture and medicine being developed as part of the Genomic Revolution.
- There is a large expenditure worldwide on health care, regardless of the country. However, in general terms, the more wealthy a country, the more it spends on health of its citizenry. Therefore, as countries become wealthier, they can be expected to devote more resources to health care issues (as well as potentially create more waste). As a consequence, the cost implications of genomic technologies for health budgets will be increasingly important to consider.
- In medicine, performing tests and running diagnostics is relatively easy. The challenge lies in the interpretation of results from these tests and deciding on the best management of health care options for an individual. While there is an increasing tendency to place greater pressure on patients to make decisions based on the data generated from improved diagnostics, it can be extremely difficult for patients to interpret complex data without advanced training. The emotion connected with making personal medical decisions also creates a risk of "decision dumping" by professionals on patients, in pursuit of giving patients full choice.
- Food and sustainable agriculture are absolutely essential components to personal and collective well-being, both economic and health. There also may be a connection between changing foods and diets and the rising rates

of conditions such as autism and congenital diseases — we just do not know. There is an urgent need to determine why rates of many of these debilitating conditions have changed so dramatically in the last several decades.

- To prepare for unknown future challenges in agriculture, it is critical that biodiversity and genetic diversity be maintained. It is also imperative to consider the importance of bees and other pollinators, and the potential detrimental effects of agricultural chemicals on these species. Improved epidemiological tools and investment in research are urgently needed to study this connection.

- Many of the food security and agriculture challenges faced by less-wealthy countries are difficult to tackle within existing economic structures (i.e., some orphan crops will never be profit-making) and intellectual property regimes (i.e., where more-wealthy countries hold the rights to crop fertility in less-wealthy countries). Dealing with these problems will require a re-examination of existing economic and intellectual property legislation. The incentives and motivations presented to private companies are often in opposition to social and/or health objectives (e.g., tobacco companies and smoking). Societal structures are also important in addressing food production challenges, especially in the case of gender equality. The role of women in farming and education (e.g., in countries where HIV has led to grandmothers taking on much of the responsibility for raising children) is key to providing food security, and has an associated impact on political stability.

- For all of the fields connected to the Genomic Revolution, a unifying issue that must be considered is the way that science is communicated. A traditional approach has been through messaging, which is perceived by the public as "advertising" for science, using simple sound bites. The public is not stupid, and wants to have information provided in terms of stories that present the balance of risks and benefits. There are difficulties faced from a policy perspective in selecting which scientific developments to pursue or apply, but the public needs help to understand how to balance these choices, especially when the taxpayer provides the funding and the next generation will reap the benefits.

Caucus statement

This summary was prepared by the ISGP from remarks made by Mr. Jim Kolbe in his role as a Caucus Leader

- The Genomic Revolution is creating a huge amount of data, and these data are clearly going to change both the food and health industries. The impact of the Genomic Revolution will be large and long lasting, although it is not possible at this time to predict the full extent of impact and the challenges it will present.
- There was consensus on the need for greater investment in food security, especially in agricultural research. Society may be on the cusp of another agricultural revolution, but dietary habits are changing and the amount of calories and food people are consuming is increasing enormously. As a result, there is a need for significantly greater food production in the future than is now sustainable. Loss of food to pests and insects is a particular concern, which needs to be addressed through the appropriate use of available tools, including genomics and pesticides. Reducing food waste via these routes would make a large impact on improving food security.
- There is wide acceptance amongst scientists and many policy makers that genetically modified food is acceptable and necessary, but this view is not matched by public perception. A key question is how this can be changed. Approaches utilizing both improved education and communication involving scientists, policy makers, and the media will be required.
- In relation to existing structures and systems, there was no agreement on the role of intellectual property (IP) with respect to food and medical applications of genomics. Clear concerns were expressed by the private sector about what incentives would exist to invest in agricultural research if IP protection was taken away or weakened. Interesting proposals were put forward for IP-free agricultural production, but these are probably unlikely to be implemented in the near future. However, there was some agreement that the food security system and food supply chain (including research, technology deployment, production practices, consumption, and waste) does not work as effectively as it should and needs to be improved.

- The explosion of data resulting from the Genomic Revolution is changing the face of medicine (e.g., through the gathering of diagnostic information, improved understanding of orphan diseases, and the availability of more specific diagnoses). Focus is now shifting from illness to wellness, including the importance of nutrition. Costs are a huge concern, and there was disagreement about whether new genomic technologies can help reduce health care costs. Genomic technologies are likely to increase demand, but health care costs will probably be shifted rather than reduced. However, there was agreement that a focus on wellness and keeping people healthy is a positive step, which can be supported by new genomic technologies and personalized medicine. Privacy is clearly an emerging concern that will need to be addressed as part of the expansion of genomic technologies.
- Trade is a major factor in all of the discussions around the Genomic Revolution. Increased and freer trade can bring about improvements in food security and medical innovation. There is a need to keep markets as open as possible and be vigilant against attempts to restrict trade.

Caucus statement

This summary was prepared by the ISGP from remarks made by Dr. Julian Huppert in his role as a Caucus Leader

- There is a disparity between the interest and investment in medicine versus agriculture. Although food is a fundamental human requirement (even more so than health care), it is often difficult to draw public attention to issues relating to agriculture and food. Public awareness of the importance of food can be increased by incorporating it into the concept of overall wellness, or even more appropriately, "well-being," which extends beyond simply not being ill or on purely physical wellness to include mental aspects.
- There are an increasing number of issues concerning the application of the precautionary principle. Of primary importance is the fact that such applications do not consider the cost of not acting, but rather focus only the cost or risk of action. A more balanced approach is needed. This is especially important for food security. People (primarily in more-wealthy countries) consider the *status quo* where abundant food is readily available will be "business as usual" long into the future. However, since the current situation is likely to change, the costs of inaction can be serious and therefore, need to be considered. It is easier to make this case in medicine (where someone is ill and the costs of inaction are clear), but rebalancing the applications of the precautionary principle is more challenging in the debate about food and agriculture, even though it is no less important.
- How scientific understanding is communicated remains an important challenge with respect to food and medical issues. It is not helpful to simply present scientists as experts who know best – "do what I say because I am the expert." Treating the public as uninformed is perceived as arrogant, and is ultimately unproductive. This problem applies to many controversial scientific and technological issues (e.g., biotechnology, nuclear energy). Scientists and policy makers need to understand and engage with the public's genuine concerns about new technologies, and resist the urge to just communicate facts. In the medical field, the impact of genomics in the digital age makes privacy a key concern that needs to be addressed. In approaching all of these aspects, it is important to include social scientists

in designing engagement strategies. An important question is: Who is responsible for communicating scientific understanding? Should it be scientists, policy makers, government officials, or representatives from industry? An effective approach will probably require the involvement of all of these groups. These issues also directly connect with a need for better science education throughout society.

- There is a need to be more realistic when considering timescales for the introduction of genomic technologies, especially in health care. In the case of agricultural biotechnology, it took approximately 30 years to progress from the early research stage to its widespread use. Genomic medicine is often presented as moving very quickly from research into clinical applications, but it will likely take as much time and experience as occurred for the agricultural applications. Since significant practical and ethical challenges can be expected as genomic technologies move into the clinic (e.g., how to inform patients to make decisions), proponents for genomic applications must be publicly realistic about when to anticipate genomics to be available publicly. Excitement and enthusiasm need to be balanced against realism by offering achievable outcomes without overpromising.
- There is also a timescale disparity between policy decisions and scientific conclusions. Policy makers work on very short timescales, especially compared to research timetables. Effectively interfacing these two groups requires reconciling this disparity in time scales.
- Much debate focused on how "open" versus "closed" research and development relates to identifying useful intellectual property. Specifically, what genomic information should be free and publicly available? A balance must be found between allowing applications to be generated more widely and quickly (but not necessarily more profitably), and allowing innovators to get a return on their investments. This is a particularly challenging issue in the agri-biotech industry.
- Regarding cost savings in health care generated by the Genomic Revolution, it seems likely that genomic technologies may produce some savings on an individual level, but that spending is likely to be transferred elsewhere. Since increased information leads to finding new conditions to treat, and new ways to treat them, in the long term, genomics will probably have little effect on overall health care spending.

Caucus Debate Summary

The application of genomic technologies to agriculture and medicine raise a number of security concerns, particularly related to infrastructure protection and narcotic proliferation. These security concerns highlight the need to broaden educational efforts to scientists themselves, who are often unaware of regulatory regimes to prevent misuse of genomic technologies. In a broader sense, national security concerns are closely linked to food security and water availability (e.g., reliance on food imports, access to groundwater sources, force protection and supply, access to food and water as drivers of conflict).

Trade issues are an important consideration for the deployment of genomic agricultural technologies. Many African countries, for example, want to be able to produce genetically modified (GM) crops, but are unable to because of fears that this will jeopardize their exports to Europe, where restrictions of the importation of GM food affect trade policies. Revised, more liberal trade issues (e.g., tariff barriers, quotas, producer subsidies) can have significant impact on the uptake of genomic technologies.

Discussions about trade led to a substantial debate about the use of the precautionary principle in setting approaches to essentially any new technology. There was wide support for the view that the precautionary principle, especially as applied in Europe, does not take account of the risks of not acting (i.e., the opportunity cost), which in the case of food production may be much more severe than any credible human health risks posed by new genomic technologies. The assumption that maintaining the *status quo* will be adequate in the future is often incorrect, particularly in the face of challenges such as population increases, water shortages, climate change, pests and diseases, loss of soil fertility, and increased deforestation. Some proposed a redefinition of the precautionary principle, and although this was seen as unlikely given its current integration into European policy making, it was agreed that a re-evaluation was warranted to ensure that innovation is not stifled. This re-evaluation would need to take account of the political and social concerns around risk, especially in European countries. In addition, the policy concerns emerging from the Genomic Revolution span the responsibilities of multiple governmental ministries or agencies, suggesting that bureaucratic and organizational reforms may be necessary to properly evaluate and regulate new technologies. It was suggested that many of these emerging technology issues are

ones of complexity, and that current institutions and governance systems may not be suitable for addressing such complex topics.

Differing views were expressed on the role and responsibilities of the private sector in introducing new genomic technologies. Some viewed the private sector with wariness, given previous examples of environmental contamination, perceived over-zealous protection of intellectual property rights (IPRs), and a failure to fully remediate or compensate for problems caused by large multinational companies. However, in the agricultural sector, large agribusinesses were presented as partners to smaller businesses and producers, and important in the economic development of less-affluent countries, driven by more professional farmers on larger landholdings. Since private companies are driven by the needs of consumers, it was stressed that both private sector and public stakeholders need to continually listen to and understand the needs and perspectives of consumers. Some participants from the private sector suggested that many of the concerns regarding the introduction of new technologies, whether in food or medicine, have been issues for many decades and are not unique to biotechnology. A significant problem for large businesses is the cost and regulatory burden of operating in smaller markets, which may actually restrict access of the most-needy communities to new technologies. The view was expressed that many of the current concerns about GM food have moved from issues of science and safety to issues of economics, economic dependence, and industrialized agriculture.

There was disagreement over an assertion that the food security system is fundamentally broken. Food is plentiful and affordable in many parts of the world, indicating that the existing food system functions relatively well. However, this situation strongly depends on which country or region is being considered, with serious risks (e.g., malnutrition, food shortages, climate change) facing less-wealthy countries. In addition, burgeoning populations and increased urbanization are anticipated to require the production and distribution of significantly more food — a demand that the current food system is unlikely to be able to accommodate. The current food security system is perhaps not broken, but it is also not sustainable.

Food producers need to be included in discussions about changes to the global food system, as they have a unique understanding of the challenges, opportunities, and risks being faced. The conversation must not be limited only to scientists, academics, and policy makers, but must engage people from less-affluent countries, and especially those experiencing food shortages.

It was widely agreed that there is a lack of investment in basic agricultural research, especially when compared with the amount spent on medical research. In particular, genomic and systems biology research is vital to achieving the

improvements needed in food production, but this expanded investment in such research must be accompanied by supportive policies and investments, as well as the involvement of social scientists and economists. There is also a need for better deployment of existing technologies and techniques (e.g., fertilizers). Genomic technologies were viewed as an important tool in a set of technologies and applications needed to improve food production.

Communication about agricultural research and technologies to the public must be informed by the views and perspectives of social scientists and communications professionals. There are opportunities for improving connections between scientists and journalists (e.g., the work done by the Science Media Centre in the U.K.) and scientists and policy makers (e.g., "POSTnotes" from the Parliamentary Office of Science and Technology). The effective communication of issues around agriculture is intrinsically linked to a critical need for improved education about science at all levels (e.g., primary/secondary school, college/university, in the general public). Especially important is the need to educate consumers about issues regarding food and nutrition, with the disparity being highlighted between trusted sources for medical information (i.e., doctors) and the lack of trusted sources for information about food. In relation to the Genomic Revolution specifically, it was highlighted that the potential of genomic technologies to provide solutions to pressing societal problems needed to be effectively communicated, especially to people in less-wealthy countries who are most acutely facing the challenges of food security and safety. However, caution should be taken to ensure that potential benefits are not over-hyped, and that taking a positive approach to highlighting benefits of the technologies does not over-promise and lead to a public backlash.

There was significant discussion about the intellectual property (IP) issues related to the Genomic Revolution. A distinction needs to be made between the "enabling technologies" that allow for new GM crop varieties or personalized medicines, and the actual products that come from these technologies. Consensus suggested that the former should be made more freely available, whereas agricultural or medical products should enjoy IP protection to allow for appropriate return on investment by private industry.

In relation to personalized medicine, privacy was viewed as a critical component to be addressed. Although privacy concerns are not new in this field and have been explored by previous efforts related to the human genome (e.g. the U.S. Genetic Non-discrimination Act, National Institutes of Health funding to study ethical, legal, and social implications of genomics), this work needs to be built upon to address new concerns that arise from the application of genomic information.

Privacy concerns relate directly to the ability to conduct increasingly refined

and personalized trials, with sample sizes as small as one individual. These studies can only be useful if data can be effectively aggregated and analyzed, but in a way that protects individual privacy. Close collaboration among patients, researchers, regulators, payers, and industry (e.g., on standards for data collection and sharing, ensuring secure data, financing drug development) is important to develop new treatments. It was also suggested that the human impact of genomics of food, and GM foods themselves, could be viewed in terms of health issues, especially due to ongoing research demonstrating the ability of dietary modifications to significantly affect the health of an individual.

Acknowledgment

Numerous individuals and organizations have made important contributions to the Institute on Science for Global Policy (ISGP) conference on *The Genomic Revolution*, convened September 6, 2013 in cooperation with the Parliamentary Office on Science and Technology (POST) within the Houses of Parliament. Some of these contributions directly supported the efforts needed to organize the invitation-only ISGP conference, and other contributions aided the ISGP in preparing the material presented in this book, including the three invited policy position papers and the summary record, without attribution, of the views presented in the discussions, critical debates, and caucuses that ensued.

We would specifically like to thank Dr. Chris Tyler, director of POST. His leadership in helping to organize and convene this ISGP conference was invaluable and greatly appreciated

The ISGP also greatly appreciates the willingness of those in the scientific and policy communities to be interviewed by the ISGP staff who organized the content of this ISGP conference. Of special significance were the efforts of those invited by the ISGP to present their views of the scientific and societal impact of genomics through their policy position papers. Their willingness to engage policy makers in the vigorous debates and caucuses that comprise all ISGP conferences was especially appreciated. The biographies of the three authors of the policy position papers that were debated are provided in this ISGP book.

The success of every ISGP conference critically depends on the active engagement of all invited participants in the often-intense debates and caucuses. The exchange of strongly held views, innovative proposals, and critiques generated from questions and debates fosters an unusual, even unique, environment focused on clarifying understanding for the nonspecialist. These debates and caucuses address specific questions related to formulating and implementing effective public and private sector policies. The ISGP is greatly indebted to all those who participated in these not-for-attribution debates and caucuses.

The members of the ISGP Board of Directors also deserves recognition for their time and efforts in helping to create a vital, increasingly relevant not-for-profit organization in addressing many of the most important societal questions associated with science and technology of our time. Their brief biographical backgrounds are presented at the end of this book.

The energetic, highly professional work of the ISGP staff merits special acknowledgment. The staff's outstanding interviewing, organizing, and writing skills remain essential to not only organizing the conference itself, but also to recording the often-diverse views and perspectives expressed in the critical debates, capturing the areas of consensus and actionable next steps from the caucuses, and persevering through the extensive editing process needed to assure the accuracy of the material published here. All of the staff members' work is gratefully acknowledged. Their biographies are provided in this book.

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Dr. George H. Atkinson
Founder and Executive Director
Institute on Science for Global Policy
November 18, 2013

The books published by the ISGP from each of its conferences listed below are available to the public and can be downloaded from the ISGP Web site: www.scienceforglobalpolicy.org. Hardcopies of these books are available by contacting Jennifer Boice at jboice@scienceforglobalpolicy.org.

ISGP conferences on, or related to, Emerging and Persistent Infectious Diseases (EPID):

- *EPID: Focus on Antimicrobial Resistance,* convened March 19–22, 2013, in Houston, Texas, U.S., in partnership with the Baylor College of Medicine.
- *21st Century Borders/Synthetic Biology: Focus on Responsibility and Governance*, convened December 4–7, 2012, in Tucson, Arizona, U.S., in partnership with the University of Arizona.
- *EPID: Focus on Societal and Economic Context*, convened July 8–11, 2012, in Fairfax, Virginia, U.S., in partnership with George Mason University.
- *EPID: Focus on Mitigation*, convened Oct. 23–26, 2011, in Edinburgh, Scotland, U.K., in partnership with the University of Edinburgh.
- *EPID: Focus on Prevention*, convened June 5–8, 2011, in San Diego, California, U.S.
- *EPID: Focus on Surveillance*, convened Oct. 17–20, 2010, in Warrenton, Virginia, U.S.
- *EPID: Global Perspectives*, convened Dec. 6–9, 2009, in Tucson, Arizona, U.S., in partnership with the University of Arizona.

ISGP conferences on Food Safety, Security, and Defense (FSSD):

- *FSSD: Focus on Food and Water*, convened October 20–23, 2013, in Lincoln, Nebraska, U.S., in partnership with the University of Nebraska.
- *FSSD: Focus on Innovations and Technologies*, convened April 14–17, 2013, in Verona, Italy.
- *FSSD: Global Perspectives*, convened October 24, 2012, in Arlington, Virginia, U.S. in partnership with George Mason University.

Biographical information of Scientific Presenters and Caucus Leaders

Scientific Presenters

Prof. Ian Crute, CBE, Ph.D.

Professor Ian Crute is Chief Scientist of the Agriculture and Horticulture Development Board. Previously, Prof. Crute served as the Director of Rothamsted Research, where he oversaw all scientific, operational, commercial, and external liaison activities of the institute. From 1973 to 1986, he was a research group leader in plant pathology at what is now Warwick-HRI (formerly Horticulture Research International — Wellesbourne). In 1986, he obtained a Fulbright Fellowship and went to the University of Wisconsin–Madison in the United States to work on the genetics of resistance to fungal pathogens. On returning to England in 1987 he moved to HRI East Malling (now East Malling Research) as Head of the Crop and Environment Protection Department. He returned to Warwick-HRI in 1993 and after two years as Head of Plant Pathology he became Director at Wellesbourne, with overall responsibility for the research direction at the site until his move to Rothamsted. Prof. Crute was awarded the Research Medal of the Royal Agricultural Society of England in 1992 and the British Crop Production Council Medal in 2006. He was elected President of the British Society for Plant Pathology in 1995, and holds a Visiting Professorship in the Faculty of Biological Sciences at the University of Oxford. His committee and board memberships include chairman of the Sainsbury Laboratory Council, member of the Lead Expert Group on the "Future of Food and Farming" Foresight project and Board member of HGCA's Crop Evaluation Ltd. Prof. Crute also is on the editorial board of a number of scientific journals including Food Security, Outlooks on Pest Management and Plant Protection Science. Prof. Crute's scientific contributions are recorded in over 160 publications.

Dr. Roger N. Beachy, Ph.D.

Dr. Roger Beachy is a professor of biology at Washington University in St. Louis, Missouri, and Executive Director of the Global Institute for Food Security, University of Saskatchewan, Canada. He is the former Director of the National Institute for Food and Agriculture, part of the United States Department of Agriculture (USDA), as well as the former Chief Scientist of USDA. Prior to this appointment, he served as the founding president of the not-for-profit Donald Danforth Plant Science Center in St. Louis, where he was responsible for setting the scientific mission of the Center.

Dr. Beachy is internationally recognized for his work in molecular virology, gene expression and for development of virus-resistant transgenic plants. Dr. Beachy is a member of a number of scientific societies, including the American Society of Plant Biologists, the American Phytopathological Society, the American Society for Biochemistry and Molecular Biology, the American Society for Virology, and formerly served as President of the International Association for Plant Biotechnology. Dr. Beachy is a member of the United States National Academy of Sciences, an Associate Fellow of The World Academy of Science, the National Academy of Science, India, and Indian National Science Academy, New Delhi. He has received a number of awards, including the Wolf Prize in Agriculture, the Common Wealth Award, amongst others. Dr. Beachy was recipient of the named R&D Magazine's Scientist of the Year for 1999. In 2003, he was elected Councilor for the National Academy of Sciences and served as a member of the editorial board of the Proceedings of the National Academy of Sciences. Research under Dr. Beachy's direction has led to a number of issued patents and pending applications. He has edited or contributed to 50 book articles, and his work has produced more than 230 journal publications.

Dr. Leroy Hood, Ph.D.

Dr. Leroy Hood is the President and Co-founder of Institute for Systems Biology and a pioneer in the systems approach to biology and medicine. Dr. Hood's research initially focused on fundamental biology and on bringing engineering and biology together through the development of five instruments — a DNA sequencer, a DNA synthesizer, a protein sequencer, a peptide synthesizer, and an ink jet printer for DNA arrays — all of which have since been commercialized. Dr. Hood has played a role in founding more than 14 biotechnology companies, including Amgen, Applied Biosystems, Darwin, Accelerator Corp., and Integrated Diagnostics Inc.. He is a member of the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine. He is also a member of the American Philosophical Society and a Fellow of the American Academy of Arts and Sciences. He is the recipient of numerous awards, including the Lasker Award for Studies of Immune Diversity, the Kyoto Prize in advanced technology, the Heinz Award for pioneering work in Systems Biology, and the prestigious NAE 2011 Fritz J. and Delores H. Russ Prize for automating DNA sequencing that revolutionized biomedicine and forensic science. He received the 2011 National Medal of Science, which was awarded to him during a White House ceremony in February 2013. His work has been widely published, and he has co-authored numerous textbooks in biochemistry, immunology, molecular biology and genetics, as well as a book on the human genome project "The Code of Codes." In addition, Dr. Hood has published more than 700 peer-reviewed articles and currently holds 36 patents.

Caucus Leaders

Prof. the Baroness Ilora Finlay of Llandaff

Professor Ilora Finlay, Baroness Finlay of Llandaff, is a Welsh doctor and professor of palliative medicine at Cardiff University School of Medicine. She is also consultant at the Velindre Cancer Centre in Cardiff, and serves as a Vice President of Marie Curie Cancer Care. Prof. Finlay was formerly the president of the Royal Society of Medicine from 2006–2008. A former Vice Dean of Cardiff University's School of Medicine, Professor Finlay was made a life peer in the House of Lords as Baroness Finlay of Llandaff in 2001. As a Crossbench member of the House of Lords, she was named as 2008 Woman Peer of the Year.

Mr. Jim Kolbe

Mr. Kolbe is a Senior Transatlantic Fellow of The German Marshall Fund of the United States. He served as a congressman in the United States House of Representatives for Arizona's 5th and 8th congressional districts from 1985 to 2007. Before joining the U.S. Congress, he served in the Arizona State Senate. Mr. Kolbe completed his B.A. in Political Science at Northwestern University and his M.B.A. with a concentration in economics at Stanford University. He is a member of the ISGP Board of Directors and is a Senior Advisor at McLarty Associates, a strategic consulting firm.

Dr. Julian Huppert

Dr. Julian Huppert is the Member of Parliament for Cambridge in the House of Commons and a member of the Parliamentary Office of Science and Technology Board. He assumed office in May of 2010. He currently sits on the Home Affairs Select Committee. He is a Fellow at Clare College, Cambridge, a former Research Councils U.K. Academic Fellow at the University of Cambridge, and a former Councillor on the Cambridgeshire County Council. He completed his B.A. at Cambridge University and his Ph.D. in Biological Chemistry at Trinity College.

Biographical information of ISGP Board of Directors

Dr. George Atkinson, Chairman

Dr. George Atkinson founded the Institute on Science for Global Policy (ISGP) and is an Emeritus Professor of Chemistry, Biochemistry, and Optical Science at the University of Arizona. He is former head of the Department of Chemistry at the University of Arizona, the founder of a laser sensor company serving the semiconductor industry, and Science and Technology Adviser (STAS) to U.S. Secretaries of State Colin Powell and Condoleezza Rice. He launched the ISGP in 2008 as a new type of international forum in which credible experts provide governmental and societal leaders with the objective understanding of the science and technology that can be reasonably anticipated to help shape the increasingly global societies of the 21st century. Dr. Atkinson has received National Science Foundation and National Institutes of Health graduate fellowships, a National Academy of Sciences Post Doctoral Fellowship, a Senior Fulbright Award, the SERC Award (U.K.), the Senior Alexander von Humboldt Award (Germany), a Lady Davis Professorship (Israel), the first American Institute of Physics' Scientist Diplomat Award, a Titular Director of the International Union of Pure and Applied Chemistry, the Distinguished Service Award (Indiana University), an Honorary Doctorate (Eckerd College), the Distinguished Achievement Award (University of California, Irvine), and was selected by students as the Outstanding Teacher at the University of Arizona. He received his B.S. (high honors, Phi Beta Kappa) from Eckerd College and his Ph.D. in physical chemistry from Indiana University.

Ms. Loretta Peto, Secretary/Treasurer

Ms. Loretta Peto is the Founder and Managing Member at Peto & Company CPA's PLLC. She has experience in consulting on business valuation and litigation, estate and gift tax, marital dissolution and employee compensation, consulting with closely held businesses regarding business restructure, cash management, succession planning, performance enhancement and business growth, and managing tax-related projects, including specialty areas in corporate, partnership, estate and gift tax, business reorganizations, and multistate tax reporting. She is a Certified Public Accountant and accredited in Business Valuations. She is a member of the Finance Committee and Chair of the Audit Committee at Tucson Regional Economic Opportunities. She also is a member of the DM50 and Tucson Pima

Arts Council. She received a Master of Accounting — Emphasis in Taxation degree from the University of Arizona in 1984, and was awarded the Outstanding Graduate Student Award.

Dr. Janet Bingham, Member

Dr. Janet Bingham is President and CEO of the George Mason University (GMU) Foundation and GMU's Vice President for Advancement. GMU is the largest university in Virginia. Previously, she was President and CEO of the Huntsman Cancer Foundation (HCF) in Salt Lake City, Utah. The foundation is a charitable organization that provides financial support to the Huntsman Cancer Institute, the only cancer specialty research center and hospital in the Intermountain West. Dr. Bingham also managed Huntsman Cancer Biotechnology Inc. In addition, she served as Executive Vice President and Chief Operating Officer with the Huntsman Foundation, the private charitable foundation established by Jon M. Huntsman Sr. to support education, cancer interests, programs for abused women and children, and programs for the homeless. Before joining the Huntsman philanthropic organizations, Dr. Bingham was the Vice President for External Relations and Advancement at the University of Arizona. Prior to her seven years in that capacity, she served as Assistant Vice President for Health Sciences at the University of Arizona Health Sciences Center. Dr. Bingham was recognized as one of the Ten Most Powerful Women in Arizona.

Dr. Henry Koffler, Member

Dr. Henry Koffler is President Emeritus of the University of Arizona. He served as President of the university from 1982-1991. From 1982 he also held professorships in the Departments of Biochemistry, Molecular and Cellular Biology, and Microbiology and Immunology, positions from which he retired in 1997 as Professor Emeritus of Biochemistry. His personal research during these years concentrated on the physiology and molecular biology of microorganisms. He was Vice President for Academic Affairs, University of Minnesota, and Chancellor, University of Massachusetts/Amherst, before coming to the UA. He taught at Purdue University, where he was a Hovde Distinguished Professor, and the School of Medicine at Western Reserve University (now Case Western Reserve University). Dr. Koffler served as a founding Governor and founding Vice-Chairman of the American Academy of Microbiology, and as a member of the governing boards of Fermi National Accelerator Laboratory, the Argonne National Laboratory, and the Superconducting Super Collider Laboratory. He was also a board member of the Association of American Colleges and Universities, a member and Chairman of the Council of Presidents and a member of the executive committee of the

National Association of Land Grant Colleges and Universities. He was also Founder, President and board member of the Arizona Senior Academy, the driving force in the development of the Academy Village, an innovative living and learning community. Among the honors that Dr. Koffler has received are a Guggenheim Fellowship and the Eli Lilly Award in Bacteriology and Immunology.

Mr. Jim Kolbe, Member

Mr. Kolbe is a Senior Transatlantic Fellow of The German Marshall Fund of the United States. He served as a congressman in the United States House of Representatives for Arizona's 5th and 8th congressional districts from 1985 to 2007. Before joining the U.S. Congress, he served in the Arizona State Senate.. He is a member of the ISGP Board of Directors and is a Senior Advisor at McLarty Associates, a strategic consulting firm. While in Congress, he served for 20 years on the Appropriations Committee of the House of Representatives, was chairman of the Treasury, Post Office and Related Agencies subcommittee for four years, and for his final six years in Congress, he chaired the Foreign Operations, Export Financing, and Related Agencies subcommittee. He graduated from Northwestern University with a B.A. in Political Science and then from Stanford University with an M.B.A. and a concentration in economics.

Dr. Charles Parmenter, Member

Dr. Charles Parmenter is a Distinguished Professor Emeritus of Chemistry at Indiana University. He also served as Professor and Assistant and Associate Professor at Indiana University in a career there that spanned nearly half a century (1964-2010). He earned his bachelor's degree from the University of Pennsylvania and served as a Lieutenant in the U.S. Air Force from 1955-57. He worked at DuPont after serving in the military, received his Ph.D. from the University of Rochester, and was a Postdoctoral Fellow at Harvard University. He has been elected a Member of the National Academy of Sciences and the American Academy of Arts and Sciences, and a Fellow of the American Physical Society and the American Association for the Advancement of Science. He was a Guggenheim Fellow, a Fulbright Senior Scholar, and received the Senior Alexander von Humboldt Award in 1984. He has received the Earle K. Plyler Prize, was a Spiers Medalist and Lecturer at the Faraday Society, and served as Chair of the Division of Physical Chemistry of the American Chemical Society, Co-Chair of the First Gordon Conference on Molecular Energy Transfer, Co-organizer of the Telluride Workshop on Large Amplitude Motion and Molecular Dynamics, and Councilor of Division of Chemical Physics, American Physical Society.

Mr. Thomas Pickering, Member

Mr. Thomas Pickering is Vice Chairman of Hills & Co, international consultants, and Strategic Adviser to NGP Energy Capital Management. He co-chaired a State-Department-sponsored panel investigating the September 2012 attack on the U.S. diplomatic mission in Benghazi. He served as U.S. ambassador to the United Nations in New York, the Russian Federation, India, Israel, El Salvador, Nigeria, and the Hashemite Kingdom of Jordan. Mr. Pickering also served on assignments in Zanzibar and Dar es Salaam, Tanzania. He was U.S. Under Secretary of State for Political Affairs, president of the Eurasia Foundation, Assistant Secretary of State for Oceans and International Environmental and Scientific Affairs, and Boeing Senior Vice President for International Relations. He also co-chaired an international task force on Afghanistan, organized by the Century Foundation. He received the Distinguished Presidential Award in 1983 and again in 1986 and was awarded the Department of State's highest award, the Distinguished Service Award in 1996. He holds the personal rank of Career Ambassador, the highest in the U.S. Foreign Service. He graduated from Bowdoin College and received a master's degree from the Fletcher School of Law and Diplomacy at Tufts University.

Dr. Eugene Sander, Member

Dr. Eugene G. Sander served as the 20th president of the University of Arizona, stepping down in 2012. He formerly was vice provost and dean of the university's College of Agriculture and Life Sciences, overseeing 11 academic departments and two schools, with research stations and offices throughout Arizona. He also served as Executive Vice President and Provost, Vice President for University Outreach and Director of the Agricultural Experiment Station and Acting Director of Cooperative Extension Service. Prior to his move to Arizona, Sander served as the Deputy Chancellor for biotechnology development, Director of the Institute of Biosciences and Technology, and head of the Department of Biochemistry and Biophysics for the Texas A&M University system. He was Chairman of the Department of Biochemistry at West Virginia University Medical Center and Associate Chairman of the Department of Biochemistry and Molecular Biology at the College of Medicine, University of Florida. As an officer in the United States Air Force, he was the assistant chief of the biospecialties section at the Aerospace Medical Research Laboratory. He graduated with a bachelor's degree from the University of Minnesota, received his master's degree and Ph.D. from Cornell University and completed postdoctoral study at Brandeis University. As a biochemist, Sander worked in the field of mechanisms by which enzymes catalyze reactions.

Biographical information of staff

George Atkinson, Ph.D.

George Atkinson is the Founder and Executive Director of the Institute on Science for Global Policy (ISGP) and is an Emeritus Professor of Chemistry, Biochemistry, and Optical Science at the University of Arizona. His professional career has involved academic teaching, research, and administration, roles as a corporate founder and executive, and public service at the federal level. He is former Head of the Department of Chemistry at the University of Arizona, the founder of a laser sensor company serving the semiconductor industry, and Science and Technology Adviser (STAS) to U.S. Secretaries of State Colin Powell and Condoleezza Rice. In 2013, Dr. Atkinson became the president-elect of the Sigma Xi Society. Based on principles derived from his personal experiences, he launched the ISGP in 2008 as a new type of international forum in which credible experts provide governmental and societal leaders with the objective understanding of the science and technology that can be reasonably anticipated to help shape the increasingly global societies of the 21st century.

Jennifer Boice, M.B.A.

Jennifer Boice is the Program Coordinator of the ISGP. Ms. Boice worked for 25 years in the newspaper industry, primarily at the Tucson Citizen and briefly at USA Today. She was the Editor of the Tucson Citizen when it was closed in 2009. Additional appointments at the Tucson Citizen included Business News Editor, Editor of the Online Department, and Senior Editor. She also was a business columnist. Ms. Boice received an M.B.A. from the University of Arizona and graduated from Pomona College in California with a degree in economics.

Marie Buckingham, B.S.

Marie Buckingham is a Fellow with the ISGP. She received her B.S. in Public Affairs with a concentration in Environmental Management and Economics from Indiana University Bloomington. Previously, she worked at King & Spalding LLP as a project assistant under the Environmental Practice Group in Washington, D.C., and also as a Sustainability Consultant to Microsoft Global in Copenhagen. She is currently applying to M.P.A. in Environmental Science and Policy programs.

Sweta Chakraborty, Ph.D.

Sweta Chakraborty is a Senior Fellow with the ISGP. She recently completed post-doctoral research on pharmaceutical regulation and product liability at Oxford University's Centre for Socio-Legal Studies and remains an active member of Wolfson College. Dr. Chakraborty received her doctorate in Risk Management from King's College London and has helped to design and co-teach a summer course in London on Managing Hazards in Europe and the United States with Indiana University's School of Public and Environmental Affairs. Her undergraduate degrees are in Decision Science and International Relations from Carnegie Mellon University.

David Miller, M.B.A.

David Miller is a Scientific/Program Consultant with the ISGP. Previously, he was Director, Medical Advocacy, Policy, and Patient Programs at GlaxoSmithKline, where he led the company's U.S. efforts relating to science policy. In this role, he advised senior management on policy issues, and was the primary liaison between the company and the national trade associations, Pharmaceutical Research and Manufacturers of America (PhRMA) and Biotechnology Industry Organization (BIO). He also held management positions in business development and quality assurance operations. Mr. Miller received his B.S. in Chemistry and his M.B.A. from the University of North Carolina at Chapel Hill.

Raymond Schmidt, Ph.D.

Ray Schmidt is a Senior Fellow with the ISGP. In addition, he is a physical chemist/chemical engineer with a strong interest in organizational effectiveness and community health care outcomes. While teaching at the university level, his research focused on using laser light scattering to study liquids, polymer flow, and biological transport phenomena. Upon moving to the upstream petroleum industry, he concentrated on research and development (R&D) and leading multidisciplinary teams from numerous companies to investigate future enhanced oil recovery ideas and to pilot/commercialize innovative recovery methods in domestic and foreign locations. Dr. Schmidt received his Ph.D. in chemistry from Emory University.

Ramiro Soto

Ramiro Soto is a Fellow at the ISGP. He currently is an undergraduate student at the University of Arizona College of Science seeking a Bachelor of Science degree in General Applied Mathematics. Beyond his academic curriculum, he is an active member of the Pride of Arizona marching band since 2010 and a member of the athletic pep band. He completed an internship with the Walt Disney Company Parks and Resorts segment in 2011. After completing his undergraduate education, he plans to apply for a doctoral program furthering his studies in mathematics.

Chris Tyler, Ph.D.

Chris Tyler is Director of the U.K.'s Parliamentary Office of Science and Technology (POST). He joined POST in 2012 having spent the previous two years as Executive Director of the Centre for Science and Policy at the University of Cambridge. Chris previously worked at the House of Commons, where Dr. Tyler was science adviser to the Science and Technology Select Committee for three years, and for Science About Science, a charity promoting science in public debates. Chris has a degree in anthropology from the University of Durham and a Ph.D. in biological anthropology from the University of Cambridge. He sits on the Board of the Campaign for Science and Engineering and several advisory boards.

Nadine Walters, D.M.S.

Nadine Walters has worked at the House of Commons since August 2004 and joined the POST in 2007. She currently is Publications and Events Manager, organizing, planning, and promoting POST's popular parliamentary meetings, which cover a wide range of topics and vary in scale from small discussion groups to large exhibitions. She is also responsible for publishing POST's flagship science and policy briefings, POSTnotes. She has a post-graduate diploma in management from the Southbank University in London.

Matt Wenham, D.Phil.

Matt Wenham is Associate Director of the ISGP. He formerly was a postdoctoral research fellow at the National Institutes of Health in Bethesda, Maryland. His research involved studying the interaction of protein toxins produced by pathogenic E. coli strains with human cells. Dr. Wenham received his D. Phil. from the Sir William Dunn School of Pathology, University of Oxford, United Kingdom, where he was a Rhodes Scholar. Prior to this, he worked in research positions at universities in Adelaide and Melbourne, Australia. Dr. Wenham received his bachelor's and honors degrees in biochemistry from the University of Adelaide, South Australia, and holds a Graduate Diploma of Education from Monash University, Victoria.