

Strengthening Regulatory Frameworks to Fuel Health Technology Innovation

Expert Roundtable

In June 2012, global leaders from science, industry, and policy gathered at the Pacific Health Summit on “Affordability and Technologies for Health” to discuss the role of technology in global health, innovative approaches to improving access to technology, and ways in which to foster a value-driven approach to the development of technologies for health. Over the course of the two days, the topic of regulation was a common theme.

As a follow-up to these conversations, NBR spoke with global health and regulatory leaders from all sectors about the current regulatory environment for health related technologies. Together, they touch on the challenges and opportunities in the regulatory field to improving the quality, safety, and efficacy of health technologies, while fast-tracking critical health technologies to save lives.

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Q. What are some of the key weaknesses of current regulatory frameworks for health technologies, and what is the role of the regulator?

Rhona Applebaum

A System that Tends to Cripple Regulators with Inactivity

It depends on the government, but under most systems, regulators are often reluctant to make quick decisions (and quick is a relative term) absent what they view as complete information. With that, the time required for approvals or reviews often extends beyond the timeframe codified in the regulations. Consequently, the regulatory process, and the regulators themselves, can be seen as risk averse, which is often not in the best interest of public health. There is a general assumption that doing nothing is risk free because we haven't articulated the fact that not doing anything actually carries greater risks. How do we address this issue? At the end of the day we must ask ourselves: who do the regulators work for? Ultimately, they work for the public. Therefore, there needs to be more fact-based communication that's customized to whomever you're trying to educate, whether it be the public or the regulators themselves, about the human need to drive innovation forward.

“There is a general assumption that doing nothing is risk-free because we haven't articulated the fact that not doing anything actually carries greater risks.”

Yot Teerawattananon

The Need for Clearly Established Regulatory Frameworks

The regulatory environments for different health technologies vary widely. Currently, the regulatory system for market approval and post-marketing surveillance for pharmaceuticals is well-established, but this is not the case for medical devices and diagnostics. Additionally, the lack of a clear regulatory framework for advanced health biotechnology, such as pharmacogenomics, gene therapy, or tissue engineering is an even more serious and complicated issue because

Rhona Applebaum

many advanced health biotechnologies do not fall into the classic categories determined by regulatory agencies. Thus, it is challenging for healthcare systems to strengthen regulatory functions for medical device regulation and create new regulatory mechanisms for advanced health biotechnology.

Patricia Mechael

Keeping up with Innovation Outside of the Realm of “Traditional” Health Technologies

Regulatory frameworks are greatly needed to ensure that health technologies are in fact improving health. Unfortunately, they often function much more slowly than the innovations they are intended to assess and approve. The role of the regulator is to evaluate the ability of new

technologies to improve health outcomes while weighing their potentially harmful effects.

Particularly, in relation to the emerging trends in the use of information and communication technologies for health or eHealth, and increasingly mobile technologies or mHealth, regulatory frameworks have not kept speed with technology innovation. This is especially true for hardware and devices that were not developed for health specifically, but through creative, systematic use and software, can now be considered health technologies.

The results are two-fold. First, new players in the gaming field are “gaming” the system by developing products that have a health dimension, but are not self identified as health technologies, and therefore bypass the regulatory process. Second, those who are in the health technologies and devices fields are shying away from the development of such systems out of fear that their technologies will not reach market fast enough and/or that stringent regulations will render products not approvable. This limbo impedes the potential that disruptive technologies—such as mobile phones, sensors, and grid network systems—have to offer in unfortunate ways, particularly as they are well positioned to improve access, quality, and cost of healthcare.

Mark Walport

Asymmetric Accountability that Impedes Efficiency

We will never get proper regulation while the accountability system for regulators is wrong. The problem with accountability for regulators is that it's asymmetric. The regulator will likely lose his or her job if he or she lets a technology through that causes harm. However, the regulator will not get into trouble if they prevent something from getting through that would have saved many lives. With this kind of asymmetric accountability regulators are incentivized

to stop things from moving forward because at the end of the day they will not be punished for that. As long as this incentive system applies, and it applies across the regulatory world, we'll never be able to improve efficiency.

Trevor Mundel

Perceptions of Regulation as an Obstacle to Saving Lives

The very notion that we perceive regulation to actually be an obstacle to saving lives is a real issue. Regulators should add value and be part of the quality system rather than an audit system, which comes after the fact and tries to establish guilt.

Mike Watson

Strengths Can Be Weaknesses

Regulators are there to ensure that the risk-benefit from the safety, efficacy, and quality of the products that they review is acceptable in the context that they are to be used. This is an essential and invaluable role that must be protected. This role is protected by the expertise of the regulators, by their independence and through clear, exacting and rigid rules and standards. However strengths can also be weakness. For instance the flip-side of the expertise of regulators is that it is almost impossible for in-house experts to be experts on everything. The challenges and opportunities lie in addressing these potential weaknesses.

Expertise can be kept broad and current by forging closer and earlier partnerships between regulators, external experts and the developers themselves. By establishing oversight of regulators their independence can be monitored to ensure that it does not drift into isolation and that it does not prevent them from being open, transparent, cooperative and realistic and finally the rigid rules and standards must be built and applied in such a way that they can be tailored to the need that is being met.

Q. Why do delays in approval processes continue to persist, and why is this such a critical issue?

Patricia Mechael

A Lack of Understanding About What Should Be Regulated

In the relation to e and mHealth, delays are often the result of a lack of understanding on the parts of the regulators and the innovators about what should or should not be regulated in relation to platforms, systems, and software; what metrics to use to assess them; and what thresholds are approvable. As technologies are developed, tested, and ready for widespread use, an immature and/or slow regulatory environment either means that technologies go to market without approval (where companies “seek forgiveness not permission”) or they stay in the laboratories where they were developed. This poses potential dangers to the general public who may not be aware of their rights and/or the rigor through which technologies ought to be vetted before they are available on the shelves for purchase.

Rosanna Peeling

The Damage Done by Significant Delays to Market Entry

I come from a diagnostics background, and in the current scenario there is a lot of tension between regulators, policymakers, and industry leaders, which results in inefficient approval processes. I’ve heard ministries of health claiming that industry is trying to sell them garbage, while the regulators are looking for someone to pin the blame on.

“Delays in the approval process should be subjected to serious examination, particularly if a technology is denied.”

This creates a very unhealthy atmosphere. In the meantime patients in developing countries are unable to access quality diagnostics that they badly need.

For example, there are currently millions of HIV infected individuals that are waiting for a CD4 test in order to know whether they’re eligible for life-saving treatment. And yet the first company that can make a point-of-care test for CD4 counting has to conduct 42 regulatory trials around the world, 29 of which are in Africa. Significant delays to market entry is damaging to both the company and the patients.

Trevor Mundel

Trevor Mundel

Regulator Incentives and Accountability

The issue of regulator incentives and accountability is very fundamental, and I think there is a certain public misperception, which is then reflected in the way that the regulators act. There is the notion that punishment is due if something is approved that is ultimately unsafe, but that if an approval of a potentially useful product is endlessly delayed, or ultimately denied, then there is really no need for consequence. I believe that delays in the approval process should be subjected to serious examination, particularly if a technology is denied. The current norm is the absolute antithesis of quality by design –that you would block something at the end of the day and not have found flaws right at the outset. There is also a notion that if it’s a private company then that’s their problem. They lost some money, \$100 million, but they can handle it. That’s not true. This is a zero-sum game. The \$100 million lost is taken out of the whole healthcare system and nation states are often paying considerable sums toward R&D investments, whether they are explicit or implicit.

Q. What suggestions do you have for improving regulatory efficiency?

Rosanna Peeling

Creating a Space to Anticipate New Technologies and Bring All the Actors Together

In the simplest sense, there are protocols and sites prepared for clinical trials once a drug is preapproved by the World Health Organization (WHO) to speed up the clinical trials process. But we need to go back one step further than getting ready for trials and proactively think about the technology design. This would inform developers about what is and isn't acceptable when you balance risk factors, public health benefit, access, and cost. If we could create a space in which we could anticipate new technologies and implement basic protocols at the design level, it would help everybody, and it would take the pressure off the regulatory agencies to be the sole people responsible when something goes wrong.

Another major problem is that regulation has not kept up with advances in technology. For example, the use of mobile phones to test blood glucose levels in diabetes patients could merge mobile technology with medical diagnostic technology, which creates a paradigm shift. All of a sudden, a cell phone has become not only a communications tool but part of a medical device. We need to have a much more proactive environment where we anticipate the technologies that will come along. Starting with all the actors in this space, we should think about not only the cost, the benefit, and the risk, but also the issues that pertain to access.

Patricia Mechael

Greater Accountability and Transparency vis-à-vis Processes and Timing

Greater clarity is needed on what is subject to regulation and what is not, along with the review process and time frames.

Greater accountability and transparency on regulatory processes and timing is needed so that innovators can build it into the design and development process. In the case of eHealth this may include collaboration across regulatory agencies—those that oversee technology and those that regulate health. At the global level, there are efforts underway by the WHO and the International Telecommunications Union to develop tools to support the development of policies,

guidelines, and regulations for eHealth at the country level. In the United States, the Food and Drug Association and the Federal Communications Commission are working together to define what constitutes various levels of mHealth technologies and the approval process for each level, depending on the technology's physiological health implications. Ministries of Health and Technology throughout the world are beginning to undertake similar processes – beginning with identifying key health priorities for which eHealth can play a role, and existing gaps in current regulatory frameworks.

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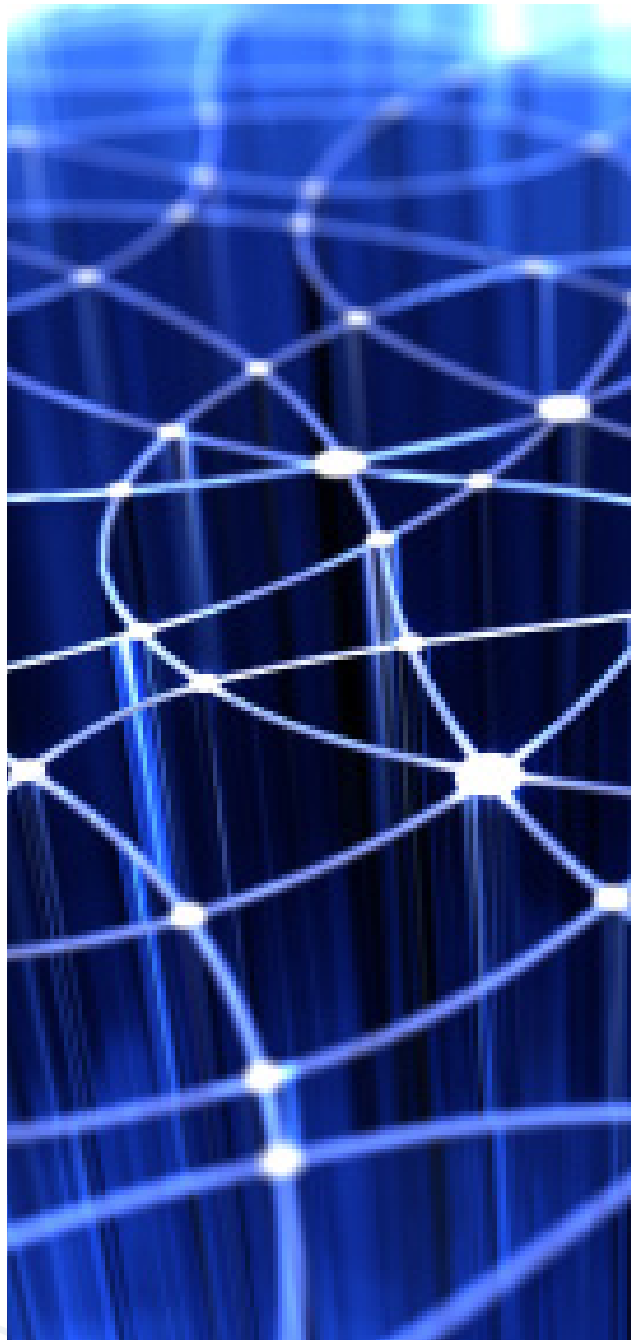
Rosanna Peeling

Trevor Mundel**Adaptive Registration to Speed Up the Approval Process**

On the innovation front there are many things that we could talk about, but one that has come up frequently is adaptive registration. This is the idea that a product that is clearly highly efficacious in phase two can receive a provisional registration that allows for the product to be launched on a registry basis into certain markets. This is intended to be done in parallel with phase three randomized controlled studies so that at the end of the day you have a broader set of safety data, and you would have real-life experience at the final registration. This option is fantastic in the developed world setting, where good systems for post-marketing surveillance are often lacking. Here you would, in one package, get exactly that data that we are critically missing to speed up the approval process.

Mitch Higashi**Quantifying the Value of New Technology Against the Risks**

I think the balancing act, as I understand it, is to maintain the regulator's essential role as the protector of public safety while expanding access to innovations and unmet needs. So I would offer a couple of suggestions for improving efficiency. Firstly, I thoroughly support the idea of adaptive registration. I would suggest that regulators and policymakers consider expanding that data source to include registries for observational data in addition to randomized trials. Secondly, I think we need to do more work to develop risk-benefit ratios so that we have a common framework to quantify the value of new technology against the risks. This would be similar to research that has been done to validate cost-effectiveness ratios and apply cost-effectiveness ratios in different settings.



Q. Is the WHO prequalification process effective for health technologies?

Peter Piot

A Need to Identify the Regulators and the Standards

Having tried to work with WHO on prequalification of antiretroviral drugs, I found the process to be frustratingly slow. There is a need to clearly define who the regulators are and who sets the regulatory standards. I think these issues are being mixed up. I don't think that WHO can be the FDA or EMA of the world. And yet sometimes that is what is expected of them. But on the other hand, setting basic standards at the supranational level is something that we desperately need and is certainly attainable.

For prequalification, I believe that we need to shift to a different system as the current system just doesn't work. My question is: who can provide the necessary support to build a strong regulatory environment and foster institutions with the right incentives? And, is there even an appetite for this among local governments, because, in some ways shifting the regulatory systems means abdicating some state sovereignty. Then also, from the side of development agencies and of global funders, is there an appetite to invest in this as well as in the actual development of technology? Otherwise the products will end up on the shelf and nobody would benefit from them.

“In working with international medical device regulators, what we are trying to do is determine which parts of the process can be harmonized, and along with health technology assessments, ensure that improved access to safe medical devices are being matched with the appropriate services in health facilities.”

Adriana Velazquez-Berumen

Trevor Mundel

Looking at the Prequalification System to Determine Minimal Steps toward Deployment Where Needed

There is a great desire to look at the WHO prequalification

process. There are certainly some instances where it's worked pretty well. If you take the example of the Menactra vaccine, the process was actually very efficient: after approval by the national regulatory authority, which was India, the prequalification took approximately three months.¹ That was a very urgent situation.

There are number of views on this. On the one hand, once a product or an intervention has been approved by a strict authority, there's one camp which says there should be nothing else required; it should

really be directly useable. Of course, that's not entirely true. There are questions about pharmaco-genetics, and delivery situations in particular countries. So there is a certain minimal set of questions I do believe that does need to be answered.

I would say that as we re-examine the prequalification system, I would hope people would take that point of view. Once we have a strict review of a product, what would be the then minimal set of steps that are required just fit-for-purpose before we can deploy this product in the regions that we intend to deploy it?

¹ Menactra vaccine is given to people 9 months through 55 years of age to help prevent meningococcal disease (including meningitis) caused by certain strains of meningococcal bacteria. For more information visit: http://www.menactra.com/what_is_menactra_CDC_recommendations.html

Adriana Velazquez-Berumen
Harmonizing the Process with Health Technology: Ensuring That the Right Devices are Being Matched with the Appropriate Services

As the coordinator of medical devices at the WHO, I should mention that prequalification for medical devices, including diagnostics, is very different from that of medicines and vaccines. Prequalification is really directed to several priority disease areas, and we definitely don't need prequalification for all medical devices because it is not feasible and we will never finish. But, apart from ensuring quality for selected products - through the prequalification processes - bought with public money, we do need to work with regulators to strengthen their oversight on the production, distribution, and safe use of medical products. In working with international medical device regulators, what we are trying to do is determine which parts of the process can be harmonized, and along with health technology assessments, ensure that improved access to safe medical devices are being matched with the appropriate services in health facilities.

Michael Gropp
Can WHO Resources keep up with Evolving Technology?

As noted by Adriana, WHO prequalification is today not widely used for medical devices. One must consider whether the current prequalification process is the best use of WHO's limited resources. Is it, for example, efficient for auditors to re-assess the manufacturer's quality management system (QMS) when that QMS has been audited, and is subject to ongoing surveillance audits, according to established international standards by recognized regulatory authorities and conformity assessment bodies in industrialized economies? How can the results of independent testing of device attributes such as electrical safety and electromagnetic

compatibility, according to international standards, be more widely accepted? Given that the product life cycle of medical devices is so much shorter than that of medicines and biologics, does WHO have the resources to keep up with evolving technologies?



Q. Is the global harmonization of regulatory standards for health related technologies a reasonable and worthwhile goal?

Rhona Applebaum

Harmonizing Equivalents, Not Wholesale Adoption

Harmonization is extremely important. The most critical concern right now in the food industry is food safety; therefore, we need to be sure that the safety regulations within each of the countries in which we operate are based on sound science and evidence. To that end, how can we harmonize the processes associated with risk assessment? It is important to remember that harmonization does not mean wholesale adoption. We should be able to harmonize what is substantially equivalent. You want something to be equivalent. It doesn't have to be identical or similar or take on the wholesale adoption approach. Harmonization does not mean adopting all U.S. regulations or all European Union regulations.

Rosanna Peeling

Balancing the Trade-Offs Between Access, Total Population Benefit, and Safety

With so many countries requiring different documentation, trials, and quality audits, we need an international body or inter-governmental body to actually manage the process of at least regional harmonization. Theoretically, harmonization is a very good thing, but I think at least for medical devices and especially for in vitro diagnostics for infectious diseases, it would be a little bit

“Harmonization offers high levels of assurance of patient safety and product quality, especially for countries with few regulatory resources.”

dangerous to have only one body that would approve both safety and effectiveness. This is because there are vast differences in the epidemiology of different diseases and strains of pathogens, which can actually render some diagnostics to be effective in one region, but not effective in another.

We need to have a serious discussion about what standards make sense at a global level and what standards should be left to local or regional regulatory bodies. I think standards for safety, for example, need to be global. But, the effectiveness of health related technologies should be regulated at the local or perhaps regional level.

Michael Gropp

Ultimately, when considering regulatory harmonization, we need to balance the trade-offs between access, total population benefit, and safety.

Patricia Mechael

Stop Reinventing the Wheel

Yes, but not at the cost of innovation and/or in a way that creates additional delays in regulatory process. Harmonizing standards at the global level with inputs from health and technology specialists and country advisors, and empowering countries to apply them, is one way of approaching this, with a global regulatory commission that could provide multi-country approval for countries that either do not have the capacity to perform regulatory reviews themselves or who are willing to acknowledge global approval.

One thing we see a great deal of in the eHealth field is duplication of effort and reinvention of the wheel, such that thousands of devices and systems are developed that do almost the same things, but that don't enable data to flow

from one to another or allow for data aggregation. For individual patients and providers, this might mean engaging with multiple remote sensing, diagnostic, treatment devices, and software applications that have undergone different and/or no review and approval processes, depending on where the technologies were developed and where they are being used. This is a dangerous waste of resources. It also complicates the use of such technologies at scale, as well as across borders, where the potential for global disease surveillance, response, and real-time monitoring are most significant. Global harmonization would help advance the move towards greater standardization within eHealth and the ability for the multiplicity of systems to have an additive impact.

Trevor Mundel

Regional Harmonization, Regional Clustering

I believe that in an ideal world, each legitimate nation state would have their own competent regulator. Now, that would be a very distant vision, but it's necessary in many cases. Even in the poorest of countries there are products that are produced locally that need some type of regulation. From a pragmatic and an efficiency perspective, I think there is rational clustering, often regional clustering, which makes a lot of sense and will help us get to this aggregation and away from the notion of a regulator of all regulators.

On the pragmatic side, in terms of harmonization the Gates Foundation recently helped kick off regional harmonization process in East Africa between five countries. We're going to test that out with two products. That type of harmonization can be very effective. The goal is to roll this out to Southern and West African regional associations. I think that regional clustering will be helpful.

Michael Gropp

Improving Access, But with Some Opportunity Cost

As the demand for, and ability to afford, medical device technologies grow in societies around the world, so too will the demand for regulatory controls. International and regional regulatory harmonization can help prevent the incremental costs of compliance with diverse requirements from growing out of proportion to the potential commercial returns. Harmonization offers high levels of assurance of patient safety and product quality, especially for countries with few regulatory resources. It also represents a consensus view of good regulatory practices and requirements, facilitates international trade, promotes use of established international standards, and encourages investment in innovation.

It is important to understand that harmonization can lead to international convergence on regulatory requirements and practices, on the evidence required to demonstrate conformity with those requirements, and on the format in which such evidence is held or presented by the manufacturer. It does not, however, imply decreased “sovereignty” or political accountability for decisions taken by national regulatory authorities.

The costs of compliance with un-harmonized regulatory requirements in the industrialized economies may “squeeze out” private sector funds that could be directed toward R&D of technologies needed in least and less developed economies. Although only one factor, ultimately, regulatory harmonization should improve the access of patients, clinicians, and health care systems around the world to safe and effective health technologies.



Q. What role do non-regulator stakeholders play in ensuring that the right technologies reach the right people for the sake of the public good?

Kalipso Chalkidou *Considering the Whole Journey*

Regulatory approval is an often necessary, but not sufficient, condition for ensuring that the necessary technologies reach those who need them most. One needs to consider the whole journey, from early development to marketing authorization and then on to pricing, listing, procurement, and reimbursement decisions, as well as appropriate (evidence-informed) use at the local level, accompanied by some mechanism for measuring uptake and impact of the technology in the context of the disease management pathway. Along this journey, the incentives may not be well enough aligned and the key players may not be the same. Affordability and access considerations need to influence the early stages of product development, long before regulatory approval.

Unfortunately, this is easier said than done. Too often, technology development and adoption is not driven by the demand side but becomes an end in itself, instead of a means to improving health outcomes and broadening access in a financially sustainable way. In low- and middle-income country settings, now building their universal coverage schemes, such an approach may have detrimental effects.

“The government needs to be a leader in protecting the health of populations. Ultimately, everybody in civil society needs to play a role and so does industry.”

Yot Teerawattananon

Yot Teerawattananon

The Role of Policymakers

Wet age-related macular degeneration (wet AMD) and diabetic macular edema (DME) are common health problems given the rapid increase of aging populations worldwide. In Thailand, thousands are blinded and have a poor quality of life due to these conditions. Two drugs—Lucentis and Avastin—both have a similar effect in not only preventing loss of sight but also improving it when used for wet AMD and DME. Avastin costs significantly (95%) less than Lucentis, but it is not officially approved for eye conditions; in fact it was created to be used with chemotherapy to treat colon cancer. Novartis, which makes Avastin, brought a case to court in the United Kingdom, saying that because

Avastin was developed to treat cancer (not macular diseases) patient safety is at risk.

The Thai government is afraid that if the less expensive drug cannot be approved for the treatment of these conditions, then blindness in Thailand will increase. So Thailand requested evidence to inform a national policy decision; we extensively reviewed that evidence and fortunately the U.S. National Institutes of Health (NIH) had already supported a head-to-head clinical trial for wet AMD. That is the most valid evidence available today because there is no incentive for industry to invest in building more evidence. It is much more difficult to prove the effectiveness of Avastin in the case of DME. But finally, the government decided to issue Avastin under the pharmaceutical reimbursement list for these two indications.

The government needs to be a leader in protecting the

health of populations. Ultimately, everybody in civil society needs to play a role and so does industry. But there are no incentives for industry to license drugs for some particular indications even if they demonstrate significant benefits, which results in the inaccessibility of many essential drugs. Addressing this should be a priority in global health.

Patricia Mechael

Engaging Stakeholders from Technologists to the End-User

As new innovations and technologies emerge, we must ensure that regulatory frameworks evolve with them and are grounded in reality. To achieve this, both the technologists as well as the user communities must be engaged in informing regulatory frameworks. Multi-disciplinary stakeholders from the public and private sectors that represent government (health and technology), technologists, health professional associations, academic and research institutions, and patient/consumer groups can help ask questions and help advise on the appropriate levels of rigor needed to advance specific technologies to market.

Michael Gropp

Understanding the Bigger Picture

The regulation of health technologies is often viewed and implemented in isolation. I suggest it should be seen as an opportunity for “joined up” policy-making. Protection and promotion of public health can coexist with encouragement of private and public investment in R&D, facilitation of trade, education policy, health care delivery policies, and economic development. We should recognize the important contribution health technologies make – not only to individual health, but to economic and social development as well.



Rosanna Peeling, Trevor Mundel, Mike Watson, Rhona Applebaum at the 2012 Pacific Health Summit (from left to right)

Q. Going forward, what do you hope to see develop in the regulatory space?

Larry Corey Public-Private Partnerships to Predefine Quality Control Standards

The quality and manufacturing technologies of the product could be done very early in the regulatory process, particularly for the pharmaceutical industry, and I think that this is amenable to harmonization. In terms of the actual clinical trial data and the interpretation of it, I'm not sure harmonization is necessarily desirable from a risk-benefit ratio, or if it is likely to be achieved from a sovereignty basis. If we can have harmonization of the manufacturing standards for products earlier, then we can actually save money as to whether clinical trials can or should be done. A global one-size-fits-all harmonization approach could be compartmentalized, probably both in diagnostics, as well as in pharmaceuticals. I think you could come up with some public-private partnerships that can work on the quality of the manufacturing issues that would predefine quality control standards, and hence speed licensure, pending clinical trial information.

“The regulator’s job is always to manage risk, and the risk of the decisions that they are going to be making. As those risks are being managed, I think it is critical to again engage all the stakeholders—from regulatory agencies and from industry, building mutual understanding across sectors.”

Kalipso Chalkidou

Linking the Regulatory Process with the Technology Development Process

Regulatory approval is only the beginning of the process of technology adoption. Fast-track marketing authorizations

for technologies that are proven to work, and not to harm, do not necessarily result in timely access for those who need them. This is why, I think, discussing regulation as a one-off activity instead of in the context of a system that includes assessments of comparative effectiveness in real-world settings, as well as judgments on affordability and value-for-money, misses the point. Access and funding are inextricably linked. Therefore, closer coordination between regulators, payers, and product-developers as well as

Stella Kilonzo

researchers, patients, and professionals, is hugely important. For example, placebo-controlled trials needed for regulatory purposes rarely provide the information that payers, service users, and professionals need to make decisions in the real world.

Finally, when it comes to making judgments on how much risk society can tolerate from introducing a new technology, appropriate incentives for regulators need to be coupled with appropriate incentives for product developers and healthcare systems, to carry out high-quality research both before and after the approval of technologies, especially where uncertainties regarding the effects of new treatments, including their safety profile, remain.

Martin Fitchet

Need for Guidelines and Guidance Around True Approaches to Disease Prevention

One of the critical challenges for me is that we in the pharmaceutical industry are heavily incentivized to treat disease but not to manage health. It actually is much easier to justify interventions and investments if we have robust guidelines at a regulatory level. There are very few guidelines that exist for interception of disease at an early level or for prevention, so it's very hard for us to understand what the approval requirements are for prevention strategies, which I think we can all agree, has to be the way forward in terms of broad global health, particularly for non-communicable diseases globally. What we really need is to work with global health authorities to develop harmonized guidelines and guidance around approaches to disease prevention. This is very important because the more regulator guidance we have, the more we'll be able to justify investments in the areas that will have the greatest impact on public health.

Stella Kilonzo

Engaging All Stakeholders

The regulator's job is always to manage risk, and the risk of the decisions that they make. As those risks are being managed, it is critical to engage all stakeholders from key institutions that interact with or impact the industry, other regulatory agencies, and industry itself with the objective being to build mutual understanding and cooperation across sectors. There is often discussion about profit versus greed. As regulators, we must not get caught up in this discussion, but rather focus on the continuous engagement of stakeholders and the collecting of data in a central repository, which will allow regulatory decisions to be made from a risk-management perspective.

Michael Gropp

Training, Motivating, and Retaining Knowledgeable Regulatory Professionals, and Finding Efficient Ways to Regulate Combination Products

I hope to see further international regulatory convergence and widespread adoption of good review practices. I also hope that good underlying regulatory practices such as openness and transparency, proportionality, predictability, and non-discrimination will become well-established. A continuing challenge is the development, motivation, and retention of knowledgeable regulatory professionals, in government and in industry, in all countries. There will be a continuing need for professional training, practice standards, and certification of regulatory professionals. It will also be important to find efficient ways of regulating emerging “hybrid” technologies such as mHealth devices based on mobile telephones and “combination products” that straddle traditional regulatory borderlines.

Patricia Mechael

Transparency, Accountability, and Adaptability to Improve Regulatory Efficiency

In newly emerging fields of health innovation there is much needed consultation and adaptability within the regulatory environment and systems for expanding and/or alleviating levels of rigor, depending on the potential risks affiliated with each technology. Greater engagement with technologists and health advisors, particularly those who will be most impacted by advancement to market or delays in approval, is needed to better inform the regulatory processes. Proactive guidance, transparency, and accountability in the approval protocols, criteria, and timelines will help designers and developers plan more effectively and shorten delays – especially for those new to the health technology field. A move towards greater harmonization will also provide a platform for countries to move from no regulation to greater regulation and protection for their citizens.

ABOUT THE CONTRIBUTORS



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Stella Kilonzo is Chief Executive of Capital Markets Authority in Kenya. Ms. Kilonzo was previously Chairperson of the East African Securities Regulatory Authorities. She is also Member of Kenya's National Economic and Social Council and Fellow of Africa Leadership Initiative East Africa. In 2011, Ms. Kilonzo was named one

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Patricia Mechael is Executive Director of the mHealth Alliance and has been actively involved in International Health for 15 years, with field experience in over 30 countries. She has worked on mHealth and eHealth research, program design and implementation, strategic planning, and policy

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Trevor Mundel is President of the Global Health Program at the Bill & Melinda Gates Foundation. He oversees the Program's efforts to harness innovations in science and technology, and leads the Foundation's research and development of solutions for health problems that have a major impact in developing countries, but get too little attention and funding. Previously, Dr. Mundel was Head of Global Development for Novartis.



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Peter Piot is Professor of Global Health and Director of the London School of Hygiene & Tropical Medicine. Previously, Dr. Piot was Director of the Institute for Global Health at Imperial College, London, Founding Executive Director of UNAIDS, and Under-Secretary-General of the United Nations. He co-discovered the Ebola virus in Zaire in 1976. He is President of the King Baudouin Foundation and was ennobled as a baron by King Albert II of Belgium in 1995.



Yot Teerawattananon is Leader and Founder of the Health Intervention and Technology Assessment Program, a semi-autonomous research institute under the Bureau of Policy and Strategy in the Office of the Permanent Secretary of Thailand's Ministry of Public Health. He previously served as Director of Pong Hospital in northern Thailand and Researcher at the International Health Policy Program.



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Mark Walport is Director of the Wellcome Trust. Before joining the Trust, he was Professor of Medicine and Head of the Division of Medicine at Imperial College London. He serves on the UK Prime Minister's Council for Science and Technology, the India UK CEO Forum, the UK India Round Table, and the advisory board of Infrastructure UK. He received a knighthood in the 2009 New Year Honours List for services to medical research.



Michael Watson is Vice President of Vaccination Policy and Advocacy at sanofi pasteur. He currently leads the sanofi pasteur HIV steering committee as well as both the Vaccines Committee and Pandemic Influenza Preparedness Group of the International Federation of Pharmaceutical Manufacturers and Associations. Dr. Watson also serves on the Board of the European Vaccines Manufacturers (EVM) and leads the EVM R&D Group. Prior to his current role, Dr. Watson was Executive Vice President of Research and Development at Acambis.

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