

Expediting Patient Access to New Medicines: A Call to Action, London, January 26–27, 2010

In the last 50 years the average life span has increased by 10 years, largely due to advancements in pharmaceutical drug development, primarily within the developed world. What will drive this over the next 50 years?

Improved patient access to drugs is a critical goal for all stakeholders in drug discovery, development, and delivery. However, drug access levels for patients continue to decrease, driven by, for example, stricter regulatory policies, lower R&D output, stronger payer cost pressures, and a complex legal environment. Given the importance of health and well-being, it is critical for stakeholders to better understand these hurdles and develop high-impact solutions that significantly increase patient access to new medicines. While pharmaceutical companies have had some limited success in overcoming R&D hurdles, a multistakeholder holistic approach is necessary to develop paradigm-changing solutions.

A meeting of 12 distinguished health care experts was convened on January 26–27, 2010, in London, UK, to address this issue. The participants included government regulators, health care policy experts, industry leaders, health economists, health care attorneys, patient advocates, and academics. The primary objectives of the meeting were to further understand the hurdles to patient access and to develop high-impact global solutions. Topics discussed included the following:

- The nature of the problem
- Initiatives currently underway
- Insights on the challenges and barriers that inhibit patient access to new and innovative medicines
- Prioritizing ideas to facilitate meaningful strategies for expediting patient access to new medicines

- A potential path forward for implementing the priority ideas from the meeting

Five of the ideas that were discussed are as follows:

1. A nonprofit, independent, patient-driven drug assessment agency to provide an appraisal of risks versus benefits of new drugs to both individuals and the society as a whole, unbiased by nonclinical measurements such as the quality adjusted life year (QALY)
2. An academic institute of regulatory science to drive research into the discipline of drug regulation
3. A new Asia-Pacific panregional regulatory agency to provide centralized regulatory support
4. Better sharing of data within the pharmaceutical industry (eg, safety databases, genomic and small-molecule libraries, negative outcomes) directly, or potentially through government bodies
5. Enhanced use of private-public partnerships in new product development building on learning from organizations such as the Bill and Melinda Gates Foundation, the FDA Critical Path Initiative, the Innovative Medicines Initiatives, and the Cardiac Safety Research Consortium.

The column reviews important discussion and insight emerging at the meeting, and is intended as a call to action highlighting the importance of improved global patient access to new medicines. The first two of the ideas just described were viewed as top priority based on feasibility and potential impact.

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INTRODUCTION

Innovation is at the heart of humankind's well-being and a driving force behind impressive improvements in the standard of living. Over the past 50 years the advent of new medicines has

been a key driver of significant increases in life expectancy and quality. While often invented in close collaboration between academic and industrial scientists, these drugs were mostly developed and commercialized by the pharma-

ceutical industry. However, despite an ever-increasing global burden of chronic diseases, the number of applications for new medicines continues to decline and time lines to deliver drugs to patients continue to increase despite massive expansion of investments into R&D and enormous advances in understanding biological systems.

While patients, the most important stakeholders of all, have become more educated about disease, their share of voice in the benefit-risk and benefit-cost debates has not increased commensurately. Furthermore, new demographics have exacerbated other needs in terms of how we measure therapeutic impact including mortality and morbidity, ability to function, and quality of life. Addressing these issues requires novel approaches regarding the need and benefits of incremental versus breakthrough innovation. Furthermore, the voice of patients in the developing world will continue to be an important factor in this debate, one that must be considered for any solution to be complete.

An aging population in the developed world, as well as the growing life expectancy of the developing world, stands to further exacerbate the problem. For example, by 2030, individuals age 65 and over will comprise approximately one-fifth of the US population (1). While we are living longer,¹ we are also experiencing unprecedented rates of cancer, America's second leading cause of death (2). At the beginning of 2007, in the United States approximately 12 million men and women were alive who had a history of cancer of all sites (3), and as our population ages, we can expect greater numbers of us will be living with and seeking treatment for this disease.

These challenges will persist and perhaps intensify as the global population grows and the developing world continues to present increases in lifestyle diseases such as coronary artery disease, stroke, obesity, and type 2 diabetes mellitus. In the past, lifestyle diseases were diseases of the affluent, and uncommon in the developing world. It is now predicted that by 2020, these diseases will be causing 7 out of 10 deaths in developing countries (4). The devel-

oping world is now faced with a dual dilemma of having both lifestyle diseases and communicable diseases (5). Access to critical life-saving drugs will be an imperative for these nations, particularly in the midst of severe economic constraints. Given the importance of this issue and the many stakeholders involved, a holistic look is warranted to create a new paradigm for developing and delivering innovative medicines to patients. This is both a challenge and a moral duty for all stakeholders involved.

This report describes discussions at a meeting aimed at a holistic analysis of critical factors limiting early patient access to medicines, and creating a process toward the resolution of these issues. The path forward must include all relevant stakeholders, such as the biopharmaceutical and medical device industry, payers, providers, regulators, and health policy makers. Pivotal to the success of any initiative will be regulators and policy makers who can help to refine the benefit-risk equation underlying patient access to new medicines.

OVERVIEW OF THE NATURE OF THE PROBLEM

The main challenge impeding access to innovative medicine lies in the optimal assessment of benefit versus risk for new therapies from development, regulatory, and delivery perspectives. There are five key elements to the problem, described below.

DECLINING R&D PRODUCTIVITY AND OTHER INDUSTRY FACTORS

The traditional development and approval cycle of R&D in the pharmaceutical realm has seen decreasing success and increasing timelines for regulatory review, with an added impact on intellectual property (IP) protection. The result is reduced patient access to novel medicines and disincentivization of innovation in pharmaceuticals.

Likewise, the industry's perceived lack of transparency has contributed to a poor perception by the public, further complicating introduction and marketing of new products. For example, there is a need for greater transparency

of several factors including total spending on drug development (particularly those that fail to reach market), physician payments by pharmaceuticals, and total expenditure on lobbyists and relationships with policymakers.

LITIGATION ENVIRONMENT

Excessive litigation protection issues have caused physicians and manufacturers to be more risk averse in their choice of therapies to pursue. Tort considerations have been particularly important to the pharmaceutical industry in limiting the risks of high R&D investment. Highly regulated and closely watched, pharmaceutical companies have recently experienced significant setbacks. A poor public image and rising financial costs resulting from litigation around safety-related issues have become all too common. The recent *Wyeth v. Levine* case,² for example, showed that a drug with serious potential adverse effects may trigger a winning lawsuit, despite clear safety warnings on its label. Similarly, physicians suffer from the rapid growth in malpractice lawsuits. The resulting risk aversion drives pharmaceutical companies and physicians to forgo potentially attractive drugs due to potential safety concerns, thereby depriving access for the subset of patients for whom the drug could be safe and efficacious.

INTELLECTUAL PROPERTY PROTECTION

IP protection timelines have changed little in the past 15 years, resulting in shorter time on the market for most drugs due to the combined effect of longer time to approval and increased ability of generic pharmaceutical manufacturers to roll out new products. The requirements for patent protection as part of the development process further disincentivize development of drugs, especially in diseases with low commercial viability. In addition, the rise in “pay to delay” (6)—where a branded drug owner pays a potential generic competitor to delay generic introduction—only highlights the continuous defensive measures companies are taking to protect their asset prior to loss of exclusivity.

There is a great need for IP reform that allows owners of branded pharmaceuticals and gener-

ic manufacturers to have greater certainty in IP protection. In addition, alternatives to the current period of exclusivity are worth considering to encourage branded manufacturers to invest in technologies that may be more expensive to produce but enable improved benefit-risk profiles for the patient subpopulations with greatest need.

The combination of IP and tort system reform would have significant impact on medicine innovation and would provide much-needed impetus to biopharmaceutical companies to invest in innovation. Such reform would involve compelling changes and landmark legislature but represent a critical step toward expediting patient access to new medicines.

REGULATORY POLICIES

Enhanced focus on drug safety by both regulators and consumers highlights the importance of identifying patient subpopulations for whom a particular drug's benefits would outweigh the risks. As a result, drug safety standards and data demands are now more stringent.

For example, the risk evaluation and mitigation strategy program, which calls for manufacturers to collect and analyze additional information on product safety, has been legally enforceable in the United States since 2007 for a broad and expanding range of drugs. The pharmaceutical industry is slowly adapting to the demands of the evolving regulatory environment, but it has not fully internalized behavioral changes called for by more rigorous regulations.

In addition, as European regulators (eg, UK, Germany) are getting increasingly concerned about cost effectiveness of approved drugs, patient access to certain new drugs is becoming limited. In 2009, a prominent case saw Roche/Genentech deciding not to seek approval of Avastin (a cancer drug) in the UK rather than comply with local regulators' request for data required to complete a cost-effectiveness evaluation, stressing the need for closer cooperation.

PAYER COST PRESSURES

Increasing overall health care costs have resulted in cost control efforts from both gov-

ernment and private payers who seek to reimburse only for those drugs that show benefit to patients. Driven by market inefficiencies, health care costs have ballooned in the past decade, leading to increased cost consciousness. Payers (both in the EU and the US) aggressively manage drug expenses, pursuing all means at their disposal. Common strategies have included limiting patient access to expensive products, incentivizing patients to reduce demand or use cheaper alternatives, and encouraging physicians to prescribe lower-priced drugs.

There is therefore a tendency to avoid new technologies because they do not apply to all patients (in part due to the benefit-risk profile) and are more expensive. This cost-centric approach has the unintended consequence of curtailing innovation in drug development in favor of producing cost-effective therapeutics. If the industry continues along this path, we run the risk of developing less expensive medicines that are used by fewer people. In contrast, a patient-centric approach is required whereby patient subpopulations are segmented and drugs developed for patients with the most critical need although the risks associated may be greater: an opposing idea to the general mass-market approach currently taken by regulators.

In addition, the recent US legislation for health care reform is expected to continue to shape behaviors of patients, payers, providers, and drug makers. While the future broad impact of US health care reform on biopharmaceutical innovation is unclear, more people will gain access to health insurance and will enter the health care system. Indeed, some pharmaceutical companies have reduced earnings (7), partially due to the need to extend rebates to cover patient drug costs, which will force CEOs to make important trade-off decisions in drug development. This could have the long-term cascading effect of reducing spending on drug development or reprioritizing development to focus on cost effectiveness and risk reduction at the expense of riskier

projects to develop innovative drugs for critical diseases.

SUMMARY OF INITIATIVES CURRENTLY UNDERWAY

While several stakeholders have experimented with a variety of strategies to overcome the hurdles of patient access to new medicines, to date few paradigm-shifting approaches have been attempted. Examples include the following.

REGULATORY POLICIES, LOWER R&D OUTPUT, AND OTHER INDUSTRY FACTORS

Game-changing discontinuous improvements in patient access to drugs call for a more concerted collaboration, both within and outside the industry. Faced with increasingly demanding regulators, many pharmaceutical companies have pursued close collaborative relationships with regulators to get more drugs to market. Regulators have also shown an acceptance of novel approaches and cooperation with outside parties. For example, the FDA-sponsored Reagan-Udall Foundation was designed to elicit and leverage industry and academic perspectives on drug development.

Since safety issues are the single most important limiting factor in bringing new medications to patients, an industry-wide consortium charged with creating a comprehensive and easily accessible safety database (eg, via the FDA's Sentinel program) could play a key role in encouraging best practice transfer, enhancing transparency, and helping avoid inappropriate investments.

Several additional changes could be tested such as increased use of biomarkers to better identify the correct patient subpopulations and surrogate endpoints, to pinpoint potential safety and efficacy concerns. Fast-forwarding techniques (eg, microdosing in humans) could enhance compound selection and disease outcomes. A differentiated, scaled, approval-to-launch approach, where only few patients are initially exposed (as is already the case in many

small phase 1 trials), could also mitigate against safety issues.

PAYER COST PRESSURES

Payers are replacing physicians as the most important gatekeepers determining what drugs patients can access. This has led to greater interaction between manufacturers and payers very early in development. The industry is also increasingly focused on proving the cost effectiveness of new medicines and devising risk-sharing mechanisms. Some pharmaceutical companies, for instance, seek to interact with payers early in the development process (sharing data and seeking their input, to build a strong health-based case for future products). Others have tried money-back guarantees and outcomes-based contracts to prove the benefit-risk value for patients.

LITIGATION ENVIRONMENT

While excessive litigation is a hallmark of the legal environment (especially in the US), discussions on health care tort reform are ongoing in an effort to cap medical damages. Limitations on these liabilities could lower barriers for pharmaceutical companies to get effective drugs with safety issues that may affect a subset of patients. This would allow for investigation and use of the drug for the subset of patients with a more favorable benefit-risk profile. Currently, there is little evidence of upcoming significant change.

One example of a potentially impactful measure is the Office of Special Masters of the US Court of Federal Claims (also known as the Vaccine Court), a no-fault system for litigating vaccine injury claims (8). These claims against vaccine manufacturers cannot normally be filed in state or federal civil courts, but instead must be heard in the court of claims, sitting without a jury. Such a body for the broader biopharmaceutical therapeutics industry could have material impact in making clear the rule of law and providing individuals a swift, flexible, and less adversarial alternative to the often costly and lengthy civil arena of traditional tort litigation.

IP ENVIRONMENT

Although the IP protection environment has remained largely stable, progress is developing in a few areas. US congressional discussions hope to extend protection timelines for biologic compounds to 7–12 years. In addition, regulatory bodies have demonstrated increased willingness to grant orphan drug status and the corresponding 7 years of exclusivity. Beyond these examples, there has not been much of a movement toward either IP or tort reform.

Overall, while noteworthy, none of these approaches has significantly enabled greater delivery of new medicines to patients. A more differentiated and impactful approach is required to create the meaningful changes at the interface of manufacturers, regulators, providers, and payers to enable patient access.

REVIEW OF DISCUSSIONS AT THE CONFERENCE

This review is divided into the following parts:

- Insights on the challenges and barriers that inhibit patient access to new and innovative medicines
- Prioritized ideas to facilitate meaningful progress against this goal
- A potential path forward for implementing priority ideas from the London meeting.

Participants agreed that the broad macro-application of benefit-risk considerations and various modalities of health care technology assessment (a multidisciplinary field of policy analysis that uses the best available scientific evidence on the medical, social, ethical, and economic implications of interventions used in health care) in the licensing and availability of new medications hampers access for special populations such as elderly patients, for whom benefit-risk expectations can differ greatly from younger patients. For this to occur, significant changes in how the regulatory agencies approach drug approval decisions are required.

A potential approach to better target the right patients who would benefit from a particular new drug could involve classifying therapies into groups with graded levels of regula-

tory benefit-risk thresholds. New drugs would thus fall into categories such as life-saving medications, chronic disease treatments, preventative therapies, and lifestyle drugs. Each of these categories would have its own benefit-risk profile that would impact regulators' view on whether or not the drug should be approved. Whatever the solution, the effort to implement it will require a broad public-private coalition to further define the problem and create multistakeholder ownership of the solutions.

PRIORITY IDEAS TO FACILITATE MEANINGFUL PROGRESS

The path to meaningful improvement in patient access to new medicines starts with a fundamental change in how regulatory agencies view and assess new drugs. The goal of these agencies should be to maximize the benefit of the patient in the 21st century, looking at patient populations holistically in terms of drug benefit-risk profiles, and not in a one-size-fits-all manner. With the burden of disease continuing to increase globally, there is a pressing need for regulatory agencies to become more flexible and risk tolerant. For example, progressive or conditional approval of drugs has not been explored in great detail and could provide untold benefits to patients with life-threatening illnesses that have no therapeutic options. A conditional approval for small, critical populations could require manufacturers to submit additional data (safety and efficacy) within a specified period based on clinical experience as a prerequisite for full approval. This potentially encourages innovation and increases patient access to new medicines for life-threatening diseases.

Given the need to develop initiatives with paradigm-changing impact on the described challenges, the conference participants identified five ideas to improve the regulatory landscape here. Ultimately, the goal is to engage a broad stakeholder group to further develop the priority ideas and drive the initiatives to fruition.

INITIATIVE 1: A NONPROFIT, INDEPENDENT PATIENT-DRIVEN NEW DRUG ASSESSMENT AGENCY

This initiative would create a patient-driven agency to evaluate new medicines.

Goal. Develop standards, metrics, processes, and best practices for evaluating drugs and clinical candidates. The agency would also provide unbiased, non-QALY-based appraisals of benefits versus risks to both individuals and the society as a whole.

Issue Addressed. Lack of an independent agency to provide unbiased benefit-risk perspectives on difficult-to-assess therapeutic drug candidates.

Such an agency would be similar to consumer protection agencies that evaluate consumer products and provide ratings on their risk or cost versus benefits. For example, it could be based in a central location and members could consist of former regulators, physicians, preeminent scientists, ex-pharmaceutical executives, and members of patient advocacy groups. The group would routinely meet to assess candidates for regulatory agency approval and provide unbiased perspectives on the efficacy and safety of the drug, risks, and suitable patient subpopulations.

An independent body like this could enable regulatory agencies to make more effective decisions on borderline drug candidates with relatively favorable risk-benefit profiles compared with most drugs. By assessing the potential therapeutic value to the most critical patients, innovative drugs that otherwise would not be approved may in fact get approved for only small subpopulations (similar to orphan drugs).

INITIATIVE 2: INSTITUTE OF REGULATORY SCIENCE

This initiative would seek to establish an institute of regulatory science, complete with faculty and a curriculum aimed toward advancing the discipline of drug regulation and approvals. Regulatory science relates the regulatory, legal, and ethical requirements of biomedical prod-

uct development to the scientific research needed to ensure the safety and efficacy of those products.

Goal. Enable continuous regulatory education and tool creating; standardize training for all graduates and help meet the demand for regulatory professionals whose backgrounds in biological, pharmaceutical, and biomedical sciences are enhanced by the knowledge and skills needed to manage regulated biomedical products.

Issue Addressed. Lack of independent research on regulatory science and drug approval; Lack of standardized training of regulatory experts; insufficient novel risk/benefit analytical processes and tools.

Such an institute could sit at a major academic institution and consist of faculty from academia, industry, and the public sector. The curriculum could include areas such as regulation of foods and medical products, quality assurance, clinical research, statistics, law, and business. Students potentially could include members of regulatory agencies, regulatory affairs leaders of biopharmaceutical companies, and lawyers. The institute could be similar to the widely available executive MBA programs afforded to business managers.

One potential impact of this agency is in creating the knowledge and skills to enable conditional or progressive drug approval. Another benefit of the regulatory science research conducted could be the creation of cooperation models to compare different regional agencies along several performance metrics. Examples of performance metrics would include number of annual approvals, approval times, efficient use of safety assessments, pharmacovigilance tools and infrastructure, resource levels, IT system upgrades, and training of reviewers. This would foster positive competition among the agencies, leading to superior performance.

INITIATIVE 3: NEW ASIA-PACIFIC PANREGIONAL REGULATORY AGENCY

This initiative envisions the creation of a new regulatory agency in the Asia-Pacific region

that would provide centralized regulatory support for these regions outside of North America, Japan, and Europe.

Goal. Create an agency with sufficient resources and scale to accelerate drug approval in a region for which drugs are not usually designed.

Issue Addressed. Lack of centralized regulatory process and resources outside of the developed world and also an additional route for regulator drug approval.

The first embodiment of the idea could be an Asia-Pacific regulatory agency in Singapore that serves Australasia and Asia (ex-Japan). The creation of an additional new agency (similar in scale to the FDA and EMA) would continue to drive regulatory excellence but, more importantly, serve the needs of geographies that are underserved or dependent on guidance from the developed countries. This would encourage biopharmaceutical companies to invest in innovative medicines that may have a different regulatory pathway to approval beyond the three main agencies, resulting in faster access to critical medicines in emerging markets.

INITIATIVE 4: ADVANCING SHARING OF DATA WITHIN THE PHARMACEUTICAL INDUSTRY

This initiative would build on current efforts to encourage pharmaceutical companies to share nonproprietary data such as safety databases, genomic and small molecule libraries, negative outcome data, and even proprietary placebo-arm clinical trial data directly or through government bodies. Several companies have already begun moving along this path. For example, GSK recently made a 13,500-item library of malaria compounds freely available to aid the development of new innovative treatments. The release of this data, including chemical structures and associated assay data, marks the first time that a pharmaceutical company has made public the structures of so many of its compounds in the hope that they could lead to new medicines.

Goal. Create open source medium for the industry to access unpublished data to accelerate drug development.

Issues Addressed. Need for the biopharmaceutical industry to share information that can accelerate development of new medicines. Also potential to address safety issues as companies learn from each other.

This would be an industry group consisting of representatives from each biopharmaceutical company. There would be an open invitation to all companies that are willing to contribute data to the group's database. Information from the database would only be accessible by contributors. Benefits for contributions could be linked to the value and sensitivity of the data provided. For example, extended IP protection could be provided, the length of which could be commensurate with the amount and quality of data provided.

This initiative would almost certainly be a catalyst for additional research and would reduce development timelines by preventing companies from making development errors previously experienced by their peers. The long-term effect is likely an increase in R&D innovation and output, resulting in new medicines.

INITIATIVE 5: ENHANCED USE OF PRIVATE-PUBLIC PARTNERSHIPS IN PRODUCT DEVELOPMENT

This initiative would seek to develop public-private partnerships to drive new product development. The effort would build on learning from organizations such as the Bill and Melinda Gates Foundation, the FDA Critical Path Initiative, the Innovative Medicines Initiatives, and the Cardiac Safety Research Consortium.

Goal. Enable partnerships to allow for collaboration on innovative medicines for therapeutic areas such as communicable diseases in the developing world. This would accelerate R&D for products that would otherwise be unprofitable for private companies.

Issues Addressed. Such partnerships may spread the risk of developing products for tradi-

tionally less attractive markets. It would provide access for the developing world to innovative medicines that tackle relevant unmet needs. These include preventive medicines such as vaccines and microbicides, as well as treatments for otherwise neglected diseases.

This initiative envisions public-private partnerships between foundations and governments who may hold funds and pharmaceutical companies who hold R&D expertise. The Malaria RTS,S vaccine partnership between the Malaria Vaccine Initiative (MVI) and GSK is a model that has demonstrated the potential success of such partnerships in tackling difficult therapeutic areas. MVI is a vaccine development program of PATH, an international non-profit organization working to improve global health. Established in 1999 and funded primarily by the Bill and Melinda Gates Foundation, MVI works to accelerate the development of malaria vaccines and to ensure their availability and accessibility in the developing world. Successful partnerships could have a significant impact on morbidity and mortality due to communicable diseases in the developing world. Such partnerships could also tackle other small and risky commercial markets such as those for orphan diseases.

A POTENTIAL PATH FORWARD FOR IMPLEMENTING PRIORITY IDEAS

Moving forward, conference attendees proposed the creation of working groups that would formulate and articulate a paradigm shift in the effort to enable patient access to new medicines. The working groups would be led by participants overseeing the work of three or four stakeholders aligned against the agreed-upon initiative. The following four actions were recommended:

- Further evaluate and decide on priority initiatives and ideas to implement. Determine which ideas need to be developed further, and next steps, including (a) outlining the objectives, (b) determining potential impact, (c) assessing the feasibility of each idea, and (d) offering additional ideas that may be relevant.

- Determine additional stakeholders to involve and outline a communications plan. Initial key next steps could include (a) determining how to engage a broad coalition against the prioritized objectives, and (b) selecting a neutral forum and partners to sponsor implementation efforts.
- Create working groups with a clear governance structure. Once the ideas are prioritized and stakeholders determined, small multistakeholder working groups would lead cross-group communication and plan to advance the prioritized initiatives.
- Identify resources needed and funding opportunities. The successful execution of these ideas will require additional resources, including adequate funding. One option could be to use a multiconsortium model to pursue these projects and access existing funding pools.

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NOTES

1. The average life expectancy of a child born in the United States today is 78 years. See <http://www.cdc.gov/nchs/fastats/lifexp.htm>.
2. In this 2009 case, Diane Levine successfully sued and won \$6 million from Wyeth after injection of Wyeth's Phenergan caused gangrene in her hand, despite a clear FDA-approved warning on the box naming gangrene among possible side effects.

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