

Comments of the American Autoimmune Related Diseases Association (AARDA) on the World Health Organization's (WHO) draft of a Global Strategy on Public Health Innovation and Intellectual Property

Introduction

The World Health Organization is studying a proposal to revamp the pharmaceutical research and development paradigm to ensure that more resources are targeted to find cures and treatments for the diseases of poverty. AARDA agrees in principle with the goals of the plan. However, we believe that an action plan needs to address the fundamental rights and interests of patients in developing countries while at the same time protecting patients with chronic illness in both developing and developed countries. Because chronic illnesses and infectious diseases affect all, our real challenge is access to good health care which includes, but is certainly not limited to, safe and effective treatments.

AARDA, a U.S. national nonprofit health agency dedicated to bringing a national focus to autoimmunity, the major cause of serious chronic diseases, strongly believes that medical innovation must be encouraged to create better treatments for autoimmune disease. It is estimated that one in five people suffer from autoimmune diseases, with women much more likely to be affected. Any effort to damage world-wide protections for continued innovation will have an acute effect on those with autoimmunity who have a continued need for improved medical technology. Many disease categories such as autoimmune disorders are being treated with therapies that are over 40 years old and have significant side effects.

These comments are not final and will evolve as we develop a complete statement of our concerns. Because of the limited timeframe allowed by the WHO, patient organizations were not afforded an adequate opportunity to develop a complete catalog of their concerns.

The following is a statement of our core beliefs that serve as the basis of our final comments:

(1) Patients are primary stakeholders. Many health care systems, including those in the United States, lack organized, integrated and coordinated health services. One way to allocate appropriate resources and measure the impact of treatments is to focus on patient-centered care, an approach to delivering health care that emphasizes the needs and interests of patients. This approach encourages patients to define and articulate their needs, participate in decision making, and guide care to improve quality, cost-effectiveness and outcomes. This approach also demands that policy makers take into account the interests of patients above other interests.

The current WHO draft needs to recognize that the patient must be the cornerstone of any initiative. The current draft neglects to recognize that patients must be involved in all aspects of setting health care policy including international policy. Patients are not even mentioned in the WHO draft nor, as previously stated, were any patient organizations involved in the development of the draft.

While many organizations, including activist international NGO organizations, have commented on the draft, few if any represent the patient's view. WHO needs to involve patients and their representative organizations in the development of this draft.

(2) A simplistic approach must be avoided. The IGWG initiative has generated a polarizing and political debate that is not advancing the interests of patients. The current WHO draft pits patients with chronic illness against patients with infectious illness while the goal of the initiative should be to ensure access to good health care including safe and effective treatments for all patients world-wide.

This simplistic approach fails to anticipate who will fund research and development under the WHO draft, how the dollars will be managed and how this new research and development (R&D) paradigm will provide sufficient incentives to develop needed medications and treatments.

A radical overhaul of the current R&D system seems particularly risky when the outcomes of such so-called reforms are unknown. Although more R&D is needed, the results of current innovations have made great strides in improving treatments for patients with infectious diseases in both developed and developing nations.

We doubt that nations would willingly squander their scientific capital on an uncertain proposal. Instead, the international health community should be turning its attention to solutions that have the most likelihood of succeeding. We should keep this objective in mind. The IGWG proposal is not the only solution open to us.

(3) Development of quality medical treatments should be encouraged. Ensuring access to quality health care involves several initiatives including maintaining incentives in a free market system to encourage corporations to develop quality health treatments. The current WHO draft would weaken patent protection, which in turn would weaken incentives for pharmaceutical firms to undertake innovative research that would be translated into effective medical treatments for patients around the world. This would be particularly worrisome for infectious diseases as these diseases develop drug resistance and are often dependent on new therapies to address the problem.

We do not absolve the pharmaceutical industry of its responsibility for finding solutions for the humanitarian issues surrounding the lack of access to lifesaving drugs for patients in resource poor countries. Finding these solutions needs to be incorporated into each company's business plan. Industry needs to work more collaboratively to address these needs.

The current WHO draft calls for significant changes in patent protection while ignoring the many successes and ongoing efforts already being addressed by public-private projects. We are concerned that a significant change in the patent model may undermine ongoing philanthropic efforts by industry and others through public-private partnerships. In the United States, the orphan drug program created to encourage manufacturers to develop therapies for conditions that are not prevalent in the general population has resulted in the introduction of several successful therapies that have saved lives and improved patients' quality of life.

Weakening patent protections will not help patients in developing nations gain access to necessary health care services. Weakened patent protections only open the door to the introduction of substandard products and reductions in safety

protections for patients. India is a good example of how reducing patent protections designed to encourage the introduction of less expensive medications does not ensure altruistic behavior. An Indian generic drug company introduced a generic version of Abbott's Aluvia drug but priced it three times higher than the price asked by Abbott, the original patent holder.

Countries with weak patent protections are failing to ensure that drug manufacturing facilities meet international standards. This is leading to marketing of below-quality antibiotics that encourage the mutation of drug-resistant strains of diseases particularly harmful to patients with malaria and HIV/AIDS.

(4) All patients should have access to life-preserving therapies. This holds true no matter where they live. AARDA is concerned that reducing patent protections will lead to a weakening of the global environment for drug discovery that provides quality and life-preserving time to patients while the search for a cure continues. Studies have demonstrated that patents are not a barrier to ensuring that patients have access to essential medicines.

The real problem is much more complex. The overwhelming poverty, corruption within the government and social systems, lack of state-financed health care, lack of medical personnel and inadequate transport and distribution infrastructures are the biggest barriers to access.

(5) Innovation and patent protections go hand in hand. Patients benefit from health care delivery systems that foster innovation and work to translate innovation from the clinic to the bedside. The current plan is shortsighted and fails to reconcile the need for strong discovery incentives and the need for affordable access without degrading investment capital.

It is vital that the drug pipeline not be stymied. Weakening patent protections could potentially decrease the availability of essential drugs needed to treat infectious diseases including HIV/AIDS, malaria and tuberculosis. While antibiotics and other antimicrobials have played an important role in fighting infectious disease, some microorganisms have developed resistance to the drugs used against them. This would also include hospital-borne infections which have become a worldwide problem. The issue of drug resistance is a problem in developing countries with poor health care delivery systems, lack of patient compliance due to the cost of drugs and counterfeit and poor quality, parallel imported drugs.

With globalization, drug resistance now has no respect for international boundaries and poses a risk to every country including the most developed nations. While science has made progress to control and in some cases eliminate many infectious diseases, patients remain vulnerable to newly recognized and resurgent organisms. While antibiotics and other antimicrobials have played an important role in the fight against infectious diseases, some microorganisms have developed resistance to the drugs used against them. In addition, population crowding, easy world-wide travel, large-scale agriculture and the threat of bioterrorism have all raised concerns about the spread of infectious agents.

(6) Patients have a right to safe, effective treatments no matter what their diagnosis. The need for development of more effective treatments for autoimmune disease must be recognized. Although some autoimmune diseases have benefited from the introduction of new therapies, most autoimmune diseases continue to be treated with therapies introduced over 40 year ago. Many have significant side effects. A robust pipeline of innovative therapies to treat autoimmune disease is fundamental for patients residing in both developing and developed nations.

(7) Strong manufacturing and distribution controls are needed. The draft's recommendation that developing nations undertake drug discovery, conduct clinical trials and manufacture pharmaceuticals is premature. These resource-poor countries lack the basic infrastructure needed for the delivery of quality health care, education of medical personnel and policing of corruption. These unresolved issues will lead to practices that are unsafe for patients and will increase the worldwide threat to patients posed by counterfeit medications. AARDA supports the objective of supporting developing nations in research and development, clinical trials and pharmaceutical manufacturing, but only after the necessary infrastructures are in place.

(8) Intellectual property protection ensures quality medications. Each patient, no matter where he or she lives, should be protected by a regulatory system that ensures medicines are manufactured using quality, monitored processes and that the supply chain is protected from adulteration and counterfeit.

Medicines developed with patent protections perform as they are labeled and come with a guarantee of quality and effectiveness. All manufacturers, no matter whether they manufacture pharmaceuticals or toys, realize that obtaining the approval of a highly respected regulatory agency that deems the product safe and effective can ease introduction into the marketplace.

Conclusion

The needs of patients in developing countries demand a long-term solution. By focusing solely on patent protections, the WHO proposal fails to address fundamental issues that significantly contribute to the lack of access to treatments and medical care in developing countries. Before any action is taken that might impede incentives for researching new innovative therapies, the underlying issues that inhibit access to essential medicines must be addressed. Attention must be paid to the long-term consequences of reduced patent protections.

Improving health care in developing countries cannot be boiled down to a single issue. Saying that somehow patents are to blame takes the focus off the real issues: lack of infrastructure, inadequate workforce and access to health care. Any sustainable solution must address the need for increased innovation in treatments for infectious diseases. It also must consider fundamental issues such as inadequate health workforce and facilities, lack of government support for a health care delivery system, and general symptoms of poverty, such as lack of adequate drinking water that has such a profound effect on the health status of people in developing nations.

These countries must be supported so that they can invest in personnel, institutions and equipment. Developing countries need to be engaged in research and development, clinical trials and pharmaceutical manufacturing. But they first must create the infrastructure to support and implement best practices and quality assurance and to train health care personnel to ensure patient safety and effective treatment. Prevention needs to be a major focus for reduction of infectious diseases.

We offer the following recommendations:

(1) Investigate alternatives for improving access. AARDA urges the WHO to undertake a comprehensive study of many possible initiatives to improve access for those with infectious diseases and for those who live in poverty. New initiatives should build on the success of recent efforts by the private-public projects that have resulted in significant improvements in access and reduction in market barriers to many therapies. These types of programs should be encouraged and enhanced by the WHO.

(2) Develop and protect incentives to encourage medical research and development. We need to develop incentives to support research into neglected diseases such as tropical diseases and rare disorders where it has been difficult for pharmaceutical companies to recoup their costs. However, such a discussion should not overlook the fact that universal diseases such as cancer, diabetes and cardiovascular disease actually cause more morbidity and mortality in developing countries than tropical diseases.

We urge the WHO not to lose sight of its original mandate to boost research and development, build capacity and improve access, all the while making sure that the agenda is driven by patients' needs and interests.

Because of the importance of patient input AARDA joins with the member states who have requested that the decision postponed.