

## Correspondence Interview: Dr. Anthony So, MD, MPA

Jim Curry

*Dr. Anthony So serves as Professor of the Practice of Public Policy Studies at Duke University's Terry Sanford Institute of Public Policy, where he started the Program on Global Health and Technology Access in 2004. Trained as a general internist, he completed an accelerated, six-year combined BA-MD program at the University of Michigan, his Master's in Public Affairs as a Woodrow Wilson Scholar at Princeton University, his residency training at the Hospital of the University of Pennsylvania, and his postdoctoral training as a Robert Wood Johnson Clinical Scholar at UCSF/Stanford. He has formerly served as an AMSA Task Force Trustee and a senior member of AMSA Foundation's Board. He has also worked as a Senior Medical Associate at the American College of Physicians, as a White House Fellow to former HHS Secretary Donna Shalala, as Senior Advisor to the AHCPRA Administrator in supporting the Department's contributions to the President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry (and the Consumer Bill of Rights and Responsibilities), and as Associate Director of Health Equity at the Rockefeller Foundation. He now volunteers on the national board of Community Catalyst and the Advisory Board of Universities Allied for Essential Medicines.*

**GP:** Dr. So, your area of expertise in global health and technology access is fairly specialized, yet you are involved in a broad variety of advocacy, policy and academic pursuits. How did you come to choose academia and policy as opposed to clinical practice? How has that informed your current work with AMSA and UAEM to support the AffordableMedsNow.org campaign?


Originally trained and Boarded in Internal Medicine, I found clinical practice rooted my interests in public policy. Taking on increasing responsibilities for policy, it turned out that committing to a weekly clinic proved difficult, particularly in a specialty where quality care required continuity. Nonetheless, remembering the patients' interests continues to inspire my daily work in health policy. Having spent much of the past decade on the struggle over access to medicines for the developing world, giving voice to the need for affordable biologics naturally flowed from this.

Just as when special interest groups secured legislation that prevented the federal government from negotiating prescription drug prices under



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Medicare Part D, voices from the health professions need to speak out on behalf of consumers over the extended monopoly protections—twelve years of data exclusivity following FDA approval with easy renewal or evergreening —now being proposed under the guise of an abbreviated pathway for generic biologics.

**GP: In general, the greater the reward for investors, the more likely they are to invest, and at higher levels. This is the primary argument given for extended intellectual property protection, such as the proposed 12 years of data exclusivity for biologic drugs. How do we as a society balance stimulating investment and rewarding innovation with ensuring affordable access to therapeutics? Is there a point where more money for research and development doesn't translate to more and better therapeutics?**

Unfortunately, the premise that increased data exclusivity will lead to increased investment may fail to anticipate the reality. If a company can obtain twelve years of data exclusivity and then evergreen that protection with a simple tweaking of the structure of the biologic, why would it invest more in true innovation of a new biologic rather than rest on its laurels?

One also has to look more deeply at the innovation process and consider the actual consequences of extended intellectual property protection. For example, is that capital necessarily available to the innovative biotechnology firm today or to the multinational firm acquiring that biotech firm a decade or two in the future? If it is available from private venture capital markets today, is it an efficient way of investing in a public good for the future, or would it make more sense to provide public funding or low-interest capital today to accomplish the same in exchange for more affordable prices for consumers in the future?

Does more investment necessarily result proportionately in more R&D as opposed to advertising or marketing? Does more R&D investment lead to

more inventions, or is there diminishing marginal return? The General Accountability Office found that from 1993 to 2004, pharmaceutical company expenditures climbed by 147% while the new drug applications to FDA rose only 38% and the number of innovative drugs, by only 7%. We have to ask ourselves tougher questions such as whether more intellectual property protection is always better, or might it introduce more patent holdouts and thickets and hinder innovation by others? Might the means of encouraging R&D, in fact, block follow-on innovation, and are we really addressing the bottlenecks to innovation?

For the Human Genome Project, the Bermuda Rules laid out by the Wellcome Trust and the U.S. National Institutes of Health required leading publicly funded sequence centers to deposit every 1000 base pairs sequenced within 24 hours in the on-line GenBank. In so doing, the Bermuda Rules sought to protect the human genetic endowment from patenting by establishing a record of prior art. Industry as well recognizes the problem of patent thickets and holdouts. Such concerns led to the partnership between industry and academic institutions to create the Single Nucleotide Polymorphisms Consortium (SNPS), where parties could more easily cross-license these building blocks for genetic mapping.

**GP: One of the current health care reform issues in the U.S. deals with biological drugs – those made from living cells. These new pharmaceuticals are some of the most sophisticated as well as some of the highest-priced. One example is Humira, which is used to treat the symptoms of rheumatoid arthritis and can cost \$50,000 per year. What are some of the risks and benefits to pharmaceutical innovation associated with reform measures on this topic?**

The legislative intent is an important one—to establish an expedited pathway for generic approval of biologics while ensuring comparability, safety and efficacy of these follow-on products. Follow-



on competition not only would ensure greater price competition, but also greater security of the supply of biologics for our patients. When Genzyme recently encountered difficulties in its plant producing Cerezyme, the resulting shortage for patients with Gaucher disease revealed the vulnerability of sourcing this important medicine from a single manufacturer.

The problem is that the approach taken in health care reform bills before Congress—those that call for twelve years of monopoly protections after FDA approval and allow for easy evergreening of that protection—fail to accomplish these ends. The bills threaten to undermine the very follow-on innovation it purports to enable. Consumer groups as well as AMSA and UAEM have pointed out these failings. Worse yet, this level of market exclusivity further distorts R&D incentives that already fall short in addressing public health priorities. Studies cited by PhRMA on their own website show that conventional drugs, on average, require \$1.318 billion for R&D while biologics require only \$1.2 billion. Yet the healthcare reform bills with the misguided biologics provisions call for twelve years of such exclusivity for biologics, 7 more years than conventional drugs.

**GP: Over the past decade, there has been an unprecedented surge in access to essential medicines in developing countries. Previously, those same drugs were priced out of the reach of the developing world. What factors enabled this increase in access to occur, and do you expect a similar trend for biologics?**

While some gains in access to essential medicines in developing countries have occurred, we have much distance to go. Perhaps most visibly, civil society pressure and generic competition have lowered the price of AIDS drugs, but combinations of second-line drugs and pediatric formulations remain a challenge, one that the proposed UNITAID patent pool for AIDS drugs seeks to address.

Biologics include vaccines, and in recent years, significant strides in providing vaccines, particularly

for childhood diseases, have been made. When the recombinant DNA vaccine for hepatitis was introduced in the mid-1980s, the price of \$30-40 per dose was steep, but competition from plasma-derived vaccines eventually helped to bring the price down to \$1.25-2.00 per dose. Extended monopoly protections for biologics, such as those proposed in the U.S. healthcare reform bills, will make the hurdles of achieving affordable access through differential pricing that much higher. The concerns over Gleevec, an anti-cancer drug, and the HPV vaccine for cervical cancer offer some harbinger of the challenges ahead.

**GP: How have your past experiences influenced your current endeavors with the AffordableMedsNow campaign and Universities Allied for Essential Medicines?**

Having worked actively in AMSA as a medical student, I learned early on the important difference that health professionals can make in policy. OATS (old AMSA types) who had gone before us were great role models. From organizing informational sessions and paying visits to Congressional representatives to authoring op-eds and mobilizing campus call in efforts, students have made a huge difference through the AffordableMedsNow campaign. Their efforts also renew my faith that the next generation of physicians will stand vigilant for the public's and the patients' interests.

**GP: As a leader in drug research and development, the U.S. has influenced access to medicines and technologies around the world. How does US policy and law on these issues affect access to medicines in other countries? Should American pharmaceutical reform be of equal concern to citizens of other countries?**

The United States exerts considerable influence on the affordable access to health technologies abroad. Most notably, through bilateral and regional trade agreements, the U.S. government has pushed for higher levels of protection of intellectual property

rights than that demanded by the World Trade Organization's Trade-Related Aspects of Intellectual Property Rights (TRIPS). These TRIPS-plus provisions can negatively impact the availability of generics in these developing countries.

The U.S. FDA's standards also serve as an important benchmark for drug regulators around the globe. Antiretrovirals not yet generic on the U.S. market still require FDA approval under an expedited pathway to enable their purchase under PEPFAR, a U.S. government-funded aid program.

**GP: What disadvantages do developing-country pharmaceutical companies and research institutions face when competing with companies based in industrialized countries? What are some of the advantages they have?**

The disadvantages faced by developing countries reflect the asymmetry in the sharing of global knowledge. Disproportionately, industrialized countries hold most of the patents filed in key markets, have a greater share of the trained scientists, and author more scientific publications. By contrast, pharmaceutical firms in developing countries may tap into the richness of biodiversity and traditional knowledge, face lower costs in mounting clinical trials or mobilizing technical talent such as for medicinal chemistry when available, and have lower opportunity costs for taking on projects of public health priority.

GP: What types of domestic health care reform measures should students and physicians support in order to increase access to medicine and what would those reforms mean for patients once implemented?

Most specific to our discussions, students and physicians could support the legislative goals advanced by the AffordableMedsNow campaign—an authentic generic pathway for biologics with no more than five years of data exclusivity and protections against evergreening of such

monopoly protections. This would ensure greater follow-on innovation and competition for biologics.

**GP: What advice can you give to physicians in training interested in activism or patient-advocacy?**

Policy internship opportunities, research projects, and community service placements all can provide useful and complementary experiences that inform and motivate one's activism and advocacy for patients. Through the Duke Program on Global Policy and Governance, each summer we bring a cohort of highly selected and talented graduate students from a diverse range of schools and disciplines to Geneva for the Global Health Fellows Program. The Global Health Fellows complete policy internships and a one-week, intensive course on "Health Policy in a Globalizing World" co-sponsored by the World Health Organization. During the course, Global Health Fellows not only meet a diverse group of policy experts, but also make site visits to leading institutions in global health, including the Global Fund, Doctors without Borders, and UNAIDS. Programs like this help expose students to skills, substance, and social networks that will help make them future leaders in global health. Above all, there is no substitute for just getting involved and making a difference.

### About the Author

Jim Curry is a graduate of the University of Iowa. He is currently Region 10 Premed Regional Director for the American Medical Student Association (AMSA), and a Premedical Assistant for research exchange in the International Federation of Medical Students' Associations (IFMSA). Jim is a member of the AffordableMedsNow.org biologics campaign, beginning at the 2009 AMSA Global Health Leadership Institute. Jim would like to thank Laura Musselwhite, Duke medical student, for her introduction to Dr. So and ardent support of the Affordable Meds Now campaign.

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