



AMERICA'S HEALTH ECOSYSTEM IN THE EMERGING GLOBAL HEALTH MARKET

A Unique Opportunity for Growth, Employment and Better Health

Alliance for Healthcare Competitiveness
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The Alliance for Healthcare Competitiveness, representing manufacturers, health services, health IT providers, caregivers and educators, sees a unique opportunity beyond our borders. Tectonic forces of demography, economics and technology are reshaping the world's health policies and health markets, as the governments of wealthy countries struggle to manage aging populations and their developing-world counterparts seek to meet vast new demands for health care from an exploding global middle class. And America, recovering from deep recession, needs to power growth and job creation. With the right policies, America's health ecosystem can help the established developed economies in Europe and Asia continue to deliver high-quality care to their people, provide care and treatment for the emerging markets in China, India, Southeast Asia, Latin America, Africa and the Middle East, and spur growth and creation of high-wage jobs in the United States.

Why is this? The American health ecosystem includes hospitals and clinics, labs and researchers, doctors, dentists, nutritionists and nurses, insurers, manufacturers of medicines and medical devices, health IT managers and many other professions and industries. Charged with managing the health of over 300 million people in the world's most diverse nation, its different elements operate in hundreds of fields. Some help guide Americans on healthy lifestyles and prevention of illnesses and accidents; others provide the necessary care when illnesses do occur. Some finance and conduct research on every topic from HIV/AIDS to Alzheimer's, head injuries, and rare tropical diseases. Still others allow families and businesses to manage health costs, or specialize in financing that helps providers make efficient use of new technologies and offer patients a broad range of treatments. As a whole the health ecosystem is unique in the world for its scale, technical sophistication, and capacity to serve diverse populations.

As a result, the health ecosystem is a driver of America's economy. As such, rather than focusing simply on the budget challenges posed by rising health care spending, it makes sense to treat the U.S. health sector as a unique economic asset. Together, health industries and public institutions account for a sixth of American GDP, provide one in every seven private-sector

American jobs, and conduct nearly a tenth of all world research and development. The American health ecosystem is uniquely suited to help both industrialized and developing countries modernize their health care systems at scale, as they respond to the shared challenges of aging populations, the rise of chronic health conditions, and the search for more modern and effective financing and delivery of care. It is equally well-placed to help fast-growing developing nations, in which hundreds of millions of people now lack access to health care, develop ways to offer care to huge new middle classes and – especially as the advance of telecommunications creates ways to provide advice, diagnosis, care, insurance options and management over great distances – extend care to low-income and rural areas.

In this circumstances, an imaginative and ambitious trade policy centered on openness, choice, accountable and transparent regulation, cooperative research and complementary strengths can enable America's health ecosystem to offer care to a gigantic global market. Success will improve health outcomes for perhaps billions of people worldwide. And it will give America a reliable source of long-term growth, based on investment, innovation, real-economy production, exports to a growing global market, and high-quality employment.

Of course, the United States shares many health challenges facing other nations – and that is precisely what makes many of its health care solutions relevant in other settings. Every country's health care system is unique, reflecting local history, values, political decisions and social arrangements, and an ambitious health-sector trade program is not about 'exporting the U.S. health care system.' Rather it is a way to ensure that countries benefit from the sharing of leading-edge know-how, services, technologies, and products. Thus each country would not have to duplicate the multi-billion dollar capital investments in R&D and innovation that the US health economy and firms have already financed; instead, more open relationships between international health care systems are opportunities for 'win-win' propositions in which all partners find their goals easier to reach.

This White Paper is an effort to explain this opportunity, and offer a strategy to realize it.

I. EXPORTS AND THE SEARCH FOR GROWTH

As we publish this paper, America continues to grapple with the aftershocks of the economic crisis of 2008-2009. As policymakers debate domestic-policy options, the public's uncertain and somewhat pessimistic mood reflects some unhappy facts. Nearly fourteen million Americans remain unemployed. Growth remains weak. Cautious spending and home-buying habits suggest the possibility of a prolonged period of weak demand – and therefore of slow growth, slow revival of hiring, and even fear of a second recession.

These circumstances have brought a broad bipartisan agreement that exports and foreign demand can play a central role in reviving growth and job creation. The President, in fact, called for a doubling of America's exports by 2014, in his 2010 State of the Union address. This goal – and its intellectual foundation in the hope for a period of growth based on real-economy investment, innovation, production and exports – received then and continues now to receive support across the political spectrum.

But it will not easily be met, and the very fact of last year's remarkably strong export growth illustrates why. To double exports, dollar terms, means an increase from 2009's \$1.55 trillion in goods and services exports to \$3.10 trillion in 2014. In 2010, as global markets rebounded from crisis, America's exports of goods and services rose by 17%; or, in dollar terms, by \$265 billion, to a total of \$1.84 trillion.¹

In dollar figures this was the largest increase in history. In percentage terms, it was the fastest burst of real-dollar growth since 1987. Exports added 1.3 percent to GDP growth – essentially half of the 2.8 percent total GDP growth. This was the largest export contribution to growth since 1946, and the second-highest recorded since the United States began tallying GDP figures in 1929. But even if exporters match this outstanding performance in each of the next four years, the U.S. will fall short. To double exports will require not \$265 billion but \$310 billion in export growth in 2011, in 2012, in 2013, and again in 2014.

This is an ambitious goal to say the least. And if government policy is to help achieve it – whether 'it' is the specific goal of doubling exports, or a more restrained hope for a decade in which rising production for global markets compensates for weak local demand – the administration and Congress need to think on a large scale, and design trade policy accordingly. Neither adding export promotion staff in embassies, nor negotiating agreements with small countries, will by themselves suffice. Instead, trade policy as a whole will have to shift, towards a new center on those sectors of the American economy that can make contributions on the necessary scale – those relatively few sectors, in other words, which meet three tests:

- (a) Domestic production and employment on a very large scale;
- (b) Technical excellence and capacity to compete and win worldwide; and
- (c) Opportunity to serve a large, rapidly growing global market.

II. THE AMERICAN HEALTH ECOSYSTEM

The health ecosystem is one of those sectors. In fact, joined perhaps only by the information and media industries, it is the sector best-equipped to help meet the administration's export goal. A brief review of each condition – the scale of domestic production, technical excellence and international competitiveness, a growing foreign market – shows why.

1. Scale of Domestic Production and Employment

First, America's health ecosystem – with all the policy and demographic challenges it confronts – is a vast economic asset comprising well over 500,000 firms, and thousands of non-profits. Measured by dollar value and production, its combined industries are now about \$2 trillion a year. This is a sixth of the \$15-trillion U.S. economy, a third of the \$7-trillion global health industry, and roughly 3 percent of the entire \$70-trillion world economy.² To put these figures in context, America's health ecosystem is as large as the national economies of major European powers like Italy, Britain, and France, or as the combined manufacturing sectors of Japan and China.

Measured by employment, the health ecosystem is not only *a* leading employer, but perhaps *the* leading employer and fastest-growing provider of high-wage jobs. The Bureau of Labor Statistics' data show that health providers, professions, and industries employ over one American private-sector worker in seven – nearly 15 million men and women, in fields from skilled blue-collar work to scientific research, nursing, medicine, IT, management, finance and insurance, and more, with small and medium-sized enterprises accounting for a large share of employment in both services and manufacturing. This total has risen by a net of 3 million jobs since 2000, as the rest of the private-sector economy lost 6 million jobs. Health-ecosystem manufacturers like medical device-makers and pharmaceutical firms held employment steady over the past decade at 600,000 manufacturing jobs, as other manufacturers sector shed a net of 5 million jobs.³ And as of April 2011, health-ecosystem employers were advertising fully a fifth of all America's private-sector job openings.⁴

These jobs are good as well as plentiful. As Table 1 shows, health-sector industries in both manufacturing and services offer both professional and blue-collar employment at wages well above national averages.

Table 1: HOURLY WAGES BY SECTOR

Biotechnology research	\$33.94/hour
Health insurance industry	\$31.41/hour
Pharmaceutical manufacturing	\$29.98/hour
Medical-device manufacturing	\$26.86/hour
Health-care services workers	\$25.18/hour
All U.S. manufacturing workers	\$23.52/hour
All U.S. private-sector workers	\$22.87/hour

Source: Bureau of Labor Statistics, Hours, Employment and Earnings. Figures for insurance, medical devices and pharmaceuticals are for non-supervisory production workers. Data is for December 2010.

2. Technical Excellence and Global Competitiveness

Second, the American health eco-system leads the world in technical excellence, innovation in products and processes, and capacity to serve diverse populations. It is the world's unquestioned leader in research, and as such a leading creator of new ways to save lives and improve the quality of life from infancy through adolescence, childbirth and parenthood, and retirement.

American health service providers, pharmaceutical companies, and medical device-makers accounted for \$56 billion of the United States' \$242 billion in private-sector research and development in 2009, or nearly a quarter of all private-sector research.⁵ American research universities, joined by public labs like NIH and CDC, likewise dominate the world's public investment in life-science and medical research, with university medical research accounting for 33 percent of all academic R&D – a higher fraction than any other country in the world. In total, American health and medical research accounts for nearly a dime in every dollar of the \$1.15 trillion spent worldwide on R&D in all scientific disciplines combined.⁶

Direct research spending is by no means the health ecosystem's only contribution to medical science and technology. American universities in 2009 awarded over 10,000 doctorates in biomedical and health sciences – more than a third of all doctoral degrees in the sciences.

American hospitals and providers provide a vast market that helps drive innovation in other fields, from specialized software for health IT services to computers, telecom equipment, and satellites used for telemedicine.

This massive commitment to research has historically made the United States the world's center of health product innovation, the home of the most sophisticated health IT systems, the country in which health financing is most flexible and innovative, and the quickest adapter of new ways of delivering health treatments, through the use of telemedicine and other technological innovations. And the experience of serving America's large and diverse population – large elderly populations, communities of immigrants from every nation in the world, rural communities and inner cities – creates a versatility that no other health system enjoys.

Americans draw immense benefits from all of this. The jobs and growth American health industries create are of course among them – but these benefits above all come in the form of a technically excellent, flexible health care system which is innovative in technologies, administrations, insurance options, and preventive care. American public and private health research constantly creates new ways to treat and prevent diseases. Efficient insurance systems and health IT systems empower providers to make these options available to the broad public and use them at maximum efficiency. Patients with insurance can choose among new and existing treatments that serve them best. Health improves for a vast population; indirect benefits go to the entire economy, as businesses avoid unnecessary cost and lost productivity.

The technical excellence of America's health-ecosystem is equally clear abroad. America's health manufacturers serve a substantial world public. American-invented and American-made medicines, radiography machines, surgical devices, pacemakers and other tangible goods are already a leading part of our export economy. And while "health care" is sometimes considered a national and "non-tradeable" sector, health-care providers, insurers, and health IT firms also export on a significant scale, though weak data collection means the sector's contribution is little understood and undervalued in trade and commercial policy. To summarize:

Merchandise exports: Exports of health-ecosystem manufactured goods such as medical devices and pharmaceuticals topped \$70 billion in 2010. Roughly a tenth of America's manufactured exports, this total is comparable in scale to the \$120 billion in exports of all food and agricultural products combined. It is also a fast-growing export sector: health-ecosystem manufacturing exports rose by 180 percent from 2000 to 2010, five times the 37 percent growth rate for exports of all other manufactured goods.⁷

Intellectual property revenue: Commerce Department trade data regrettably offer no estimate of the health-ecosystem share of the \$36 billion American firms received in industrial-patent royalties, licensing fees, royalties, and other income from intellectual property last year. But proprietary company data suggest medicine and device patents account for a large share of this total, lower than revenue from physical exports of medicines and medical devices, but likely in the tens of billions of dollars. Revenues from health IT software likewise are not measured, but instead included in the \$36-billion total of all combined revenue from software royalties and direct sales.⁸

Health services exports – The Commerce Department’s services-trade data report \$250 billion in total commercial-services exports, but the sources of this total are at least as cryptic as those of the intellectual property revenue. The income American doctors, nurses and hospitals draw from international telemedicine, consulting visits and branches abroad is hidden in a \$116-billion “business, professional and technical services” category.⁹ Nor is any data available on health IT for foreign hospitals, contract R&D done by private and public labs and clinics, or sales of health insurance policies.

The one bit of data the Commerce Department does provide, however, suggests that health services exports may be quite large. This is medical tourism – that is, money spent by foreign patients coming to American hospitals, and American patients traveling to foreign hospitals. The Department finds \$2.6 billion in medical tourism exports in 2009 – that is, earnings from money spent by foreign patients coming to American hospitals for high-quality treatment. This is triple the \$0.8 billion the Department reports Americans spent on treatment abroad,¹⁰ suggesting a large two-way trade but one in which the United States is an especially attractive destination for the world’s patients.

3. Rapidly Growing Global Health Market

Third, the American health ecosystem has the opportunity – if policies are right and markets open – to serve a global market in which demand for innovative products and services is already high, and will grow on a colossal scale in the next two decades. According to health market analysts at Espicom, the global health care market is now at \$6 trillion, up from \$4 trillion in 2005 and likely to reach \$8.4 trillion, topping 10 percent of global GDP, by 2015.

High Export Totals to Developed-world Markets: World Bank data suggest that over three-quarters of health spending is in rich countries. These countries are, accordingly, the buyers of much of America’s health-ecosystem exports. Of last year’s \$70 billion in pharmaceutical and medical device export revenue, \$37 billion came from European Union members, \$6 billion from Japan, \$6 billion from Canada, \$3 billion from Switzerland and \$2 billion from Australia.¹¹ Governments in these and similar countries are often seeking ways to broaden patient choices and reduce budgetary pressures by reforming their national health care systems and modernizing the way patients access and receive care. American firms are able to offer high-quality care and new options in care management, funding, treatment and advice.

New communications technology is rapidly creating opportunities for health services providers, as well as financial industries and IT innovators to export on a large scale as well, as submarine fiber-optic cables and telecommunications satellites cut the cost of international telephone conversations and increase the quality of data transmission. These technologies have already created a growing telemedicine industry within the United States, enabling large urban hospitals to provide diagnosis on-line – colloquially termed “night-hawking” – to small-town and rural clinics and hospitals unable to afford full-time radiology staff. They are now bringing this innovation to the world. One case is the decision by six hospitals in France’s Brittany region to use Cambridge, Mass.-based ETIAM’s Medical Networking (SMN) technology for a regional telemedicine network. Located in a summer tourist destination, they are unable to grow and shrink with seasonal change in population, these hospitals will use SMN technology to offer

emergency, radiology and oncology departments in different institutions, exchanging medical images to enable to offer full radiological care year-round at manageable cost.¹²

Trade agreements are proven ways to amplify and accelerate this success. The sophisticated recent FTAs with Singapore and Australia, for example, went into effect in 2004 and 2005 respectively. Since then, health-ecosystem goods exports have doubled to Australia, and nearly tripled to Singapore.¹³ Overall services-export growth to these countries has been just as fast, in both cases doubling within five years, though the data regrettably permit no specific reports on the contribution of health services to this growth.

Rapid Export Growth to Low- and Middle-income Countries: With health-ecosystem exports to rich countries already large, exports to lower- and middle-income economies are rising with startling speed – reflecting, again using Espicom’s data, the doubling of the developing-country health market between 2005 and 2010. Between 2005 and 2010, for example, exports of medical devices and pharmaceuticals to China, India and Brazil, for example, nearly tripled from \$1.8 billion to \$4.5 billion.¹⁴ Sales to a long series of smaller developing countries - Peru, Colombia and Argentina; Indonesia and Vietnam; South Africa; Saudi Arabia, Qatar – grew just as fast. Many American health services industries operate and provide care, insurance, IT management and other services in these countries as well. For example, United Healthcare is now helping manage the health care for nearly one million people in India, and together with companies such as Aetna and CIGNA, is now helping US and international employers manage cross-border health care in many countries around the world.

Looming up in the near future is something far beyond anything in the American market or even today’s global health market: a fundamental transformation in demand, driven by tectonic change in demographics, economics and technology. In brief, as China, Latin America, India, Southeast Asia and other developing regions grow more affluent, more urban, and more middle-aged, the global market for more advanced health products and services is likely to quadruple from about one billion to four billion people. Some figures, summarized below in Table 2, illustrate these latter trends:

More Affluent: Middle-class people spend more on health, and the world of the next decade will be a middle-class world. The World Bank estimates that between 1981 and 2005, deep poverty rates fell from 52 percent in lower-income countries to 25 percent overall, and to rates of 10 percent in Asia, Latin America and the Middle East. By 2030, barring an unexpected sharp reversal of these trends, only 10 to 15 percent of the world’s people will be deeply poor.¹⁵ As poverty fades the middle class grows: Goldman Sachs researchers project that the global “middle class,” defined as people earning between \$6,000 and \$30,000 annually, will grow from today’s 1.7 billion to 4 billion by 2030.¹⁶

More Urban: City residents have greater access to clinics, insurance, and information that allows them to seek regular care – and the world of the next decade will be an urban world. Ten years ago, the world’s city population surpassed the rural population. By 2030 the world’s city population will rise by 1.4 billion, including a rise of 120 million in Latin America, 125 million in the ASEAN countries, 225 million in India, and 260 million in China, and account for 5 billion of the world’s 8.3 billion people.¹⁷

More Middle-Aged: Aging people require more health services - and the world of the next decade will be a middle-aged world. Between 2010 and 2030, the world's median age will rise by five years, from 29 to 34, as birthrates fall and elderly populations grow. The above-60 population, the largest consumers of health care, will double from 760 million to 1.4 billion. By region, this population will grow from 60 million to 120 million in Latin America; from 160 million to 210 million in Europe, and from 270 million to 520 million in East and Southeast Asia. The elderly population will grow by 175 million in China, 90 million in India, 60 million in the ASEAN countries. In wealthier countries growth will be only slightly slower: by 2030, over 40 percent of the Japanese population and over 30 percent of the European population will be 60 or older.¹⁸

Table 2: TWENTY YEARS TO AN URBAN, MIDDLE-CLASS, AGING WORLD

	2010	2030	Change
Global Middle Class*	1.7 billion	4 billion	135%
Population above 60	0.7 billion	1.4 billion	100%
Urban Population	3.5 billion	4.9 billion	40%
Total Population	7.0 billion	8.3 billion	19%
Population below 15	1.8 billion	1.8 billion	0%
Global Poor**	1.0 billion?	~0.5 billion?	-50%

* Population earning \$6,000 to \$30,000 per year.

** Population below \$1.25 per day, in constant 2005 dollars. Future estimates reflect tentative World Bank projections.

This more affluent, middle-aged and urban world will demand more health care –in some cases substantially more. Throughout much of the developing world, we can already see health outcomes improving. To choose just one example, 38 countries – including China, India, Nigeria, Indonesia, Brazil, Cambodia, Ethiopia, Haiti, Pakistan, and Bangladesh – have been able to cut maternal mortality rates by half over the last generation, and progress against infant mortality has been just as fast.¹⁹ And it is very reasonable to expect that this should continue.

Entering the global middle class, the people of these countries will want more and better care. In daily life they will make regular visits to clinics and hospitals for checkups and get regular care after accidents. As they become parents they will want pre-natal care and obstetrics, checkups and vaccinations, and early detection of childhood illnesses. General Electric's success in marketing low-cost baby warmers to Indian clinics is one early example.²⁰ As they and their parents age they will require treatments for cancer, Alzheimer's, bone loss and similar risks of old age.

To meet these demands, India, China, Latin America, the Middle East, Southeast Asia and Africa will all need to expand access to effective health care, public and private financial systems that promote efficiency and equity, best-in-class approaches to care management, and innovative new devices and technologies that can provide care to large lower-middle-income and rural populations. That in turn will also require modern health regulatory systems to deal with product approvals, pricing and other topics.

Telemedicine services, for example, are in some ways uniquely valuable for health care in the developing world. It can not only enable low-budget clinics to offer sophisticated services, but can also serve poorer and rural populations through “mHealth” (mobile health) programs using the mobile phone subscriptions now common throughout the developing world. (For example, even in least-developed Bangladesh, 60 million of the country’s 150 million people are cellular subscribers.) These programs range from education and awareness that can avert emergency-room visits and expensive hospital stays, to diagnostic and treatment support for those who need care, training for healthcare workers, disease and epidemic outbreak tracking, remote monitoring of pharmaceutical prescriptions, and health IT beyond the hospital.

American providers and specialist firms with expertise in telemedicine are ideally suited to create and broaden these programs. One recent case is that of Voxiva, a ten-year-old U.S. firm which links health providers to rural mobile-phone subscribers in 13 developing countries around the world. Their partnership with Mexico’s Institute of Health to develop Diabediaro, which helps improve diabetics’ adherence to treatment and can alert caregivers to urgent needs through remote monitoring via cellular phone.²¹ Any diabetic person with a TelCel cell phone can join in the program, to supplement visits to doctors and prescriptions with regular monitoring. These are the early signs of a revolution in developing-country health - m-health, telemedicine, new low-cost devices, rural care – which is already helping to make life safer and better for hundreds of millions of people.

Financing and care management may well be another area in which American capabilities can help. Consider, as one startling example, that 94 percent of Indians lack health insurance.²² This is not an untypical case; in almost all developing countries, most health spending is private rather than government, and most private health spending is out-of-pocket cash rather than insurance.²³ Countries developing national insurance systems will often choose – and often need – external expertise in operating an effective public payer system, coupled with a mix of public and private financing.

Across the spectrum of health industries, then, the higher expectations of the developing world’s people, the consequent new demand for care, and the policy reform it is bringing, represent the beginnings of a revolution. They mean not only a large and prolonged export opportunity for American products; not only a new source of demand to power American growth and innovation – but an opportunity to change health outcomes as profoundly for the better as did the vaccines, sulfa drugs, antibiotics and sanitation campaigns of the 20th century.

III. TOWARDS AN INTEGRATED HEALTH-ECOSYSTEM TRADE STRATEGY

The key now is to find the policies that sustain, broaden, and accelerate this progress – and with this we return to trade policy.

A well-designed trade strategy can enable America’s health ecosystem to offer a global middle class the high-quality health services it needs. But such a strategy will be quite different from the concepts American trade negotiators brought to health-industry issues in earlier negotiations, particularly the larger ones of the 1980s and 1990s such as NAFTA, the Uruguay Round, and China’s WTO membership.

In trade negotiations through the 1990s, American negotiators assigned to the health sector often focused on particular products and industries, with goals ranging from tariff reduction on medical devices to reimbursements for particular pharmaceuticals. A modern strategy to fit the world's demand will have a different foundation, which views the health-ecosystem as an integrated whole. Building on achievements in the more recent bilateral trade agreements with Australia, Singapore and South Korea, this would preserve negotiations on particular classes of manufactured products as an important element, but make them only one pillar in a more ambitious architecture, matched by concepts of open services markets, transparent and accountable regulatory systems, and adaptation of new technology.

All these elements would work together to support one another, as a policy designed to provide an opportunity for integrated and efficient health markets that make the most efficient use of new communications technologies, cross-border investment, choice of providers and payers, and provision of high-quality care to a vastly larger population of middle-class patients. The keystone of this strategy is the understanding that all the elements in a health ecosystem support one another – and that to open opportunities for one of them is often to improve care and create a better market for all.

To illustrate this point: Consider an opportunity for American hospitals to open branches and operate with full trading rights in a developing-world city. As the branch opens, it creates a high-quality center of service for local patients, a well-paying employer for local researchers, professionals and support staff, and a base for clinical trials and other ways to upgrade the city's medical technology. At the same time, it creates a natural buyer of American technology, a natural user of American health IT systems, and a natural telemedicine partners for U.S.-based clinics, hospitals, and health professionals. Thus many interests are advanced at once: local patients' hope for high-quality care; the local government's need for employment and technology; and the American opportunity for growth driven by new sources of demand, investment, production and exports.

An alternative illustration comes from the opportunity to export a newly invented radiological device. This is most meaningful when that device is surrounded by an array of services which are often unavailable in developing countries just developing national health-care systems. In this case, policy needs to address not only direct trade barriers, but a set of associated regulatory policies and services issues. A successful approach can improve health care in the purchasing country, and creating health-services export opportunities well beyond the actual manufacturer of the device. A list of issues to consider would include:

- *The device itself:* Tariffs, import licensing and non-tariff barriers at borders are generally minor in rich-country markets for medical devices, but can be substantial in large developing countries – often raising the price of a sophisticated device that can serve thousands of patients and reduce the general cost of illness and accident to society, and sometimes placing it out of range altogether. Trade negotiations a decade or two ago would often stop here.

- *Regulatory transparency:* Devices are obviously, however, used only when they are approved. Ministry approvals of devices for use in hospitals can be abused for nationalistic reasons, and more frequently are unpredictable and frustrating for the purchaser because processes are slow, lack transparency, lack appeals processes to a recognized higher authority, and lack avenues through which purchasers and suppliers alike can speak directly to one another about needs and costs. International standards may diverge, or be set in slow and costly ways. Both can discourage use of innovative devices and medicines, which are at times expensive but over the long term can reduce overall cost, through more rapid cures or more efficient delivery of care.
- *Financing:* Approved devices are bought when hospitals and clinics can finance them. Especially in poorer countries, hospitals interested in buying top-quality radiographical equipment will often need sophisticated lenders to finance the purchase. In both developing countries and wealthier economies, they also need payers/insurers who will reimburse hospitals for treatments that require it.
- *Electronic commerce:* A sophisticated device is a good investment when it will serve many people. If the hospital buying the device is a small one, or a clinic in a densely populated but poor rural area, it is likely to share radiological staff with other hospitals, or to have none at all. If this hospital has a guaranteed right for it to link via telemedicine to an American partner clinic, it can tap top-quality radiological diagnosis and treatment recommendations from American doctors and technicians. This means an immediate ability to serve much larger groups of patients, justifying the cost of the device through larger streams of revenue and better care.
- *Health IT systems:* Devices work most effectively and efficiently when hospitals know their patients. Detailed patient histories, for individuals and patient populations, are essential if a buyer is to use the device most effectively, track treatment over time, and provide the most effective and cost-efficient treatments.
- *Post-purchase servicing:* If the device is to be useful over long periods of time, thereby justifying a large investment, the supplier needs the ability to train hospital personnel and specialists familiar with the device and its use, manage troubleshooting and repair, and adapt the device to unique conditions in the buying country or hospital.

In these ways, an ambitious and strategic trade policy can develop the global health ecosystem, enlarge the spectrum of patient and provider choice, and bring top-quality health care to wider populations even as it supports American exports and growth.

IV. THE NEGOTIATING AGENDA

Coordinated, “coherent” opening of the full range of healthcare goods and services would thus help a growing world of middle-class patients get the choice of treatment they want, expand access to regular treatment for the rural poor, enable developing-world governments and hospitals to amortize the cost of their health expenditures over larger populations – as it enables

America's health ecosystem to invest and research more, and contribute more to growth and employment than it does today.

How in practical terms would one design a strategy to achieve this goal? Fundamentally, the U.S. government in partnership with foreign negotiating partners would need three things:

- An institutional structure which can design and sustain a health-ecosystem trade strategy over time; and
- Data and information which can help negotiators, policy analysts and private-sector stake holders more fully understand the current environment, set negotiating priorities and evaluate progress over time;
- A systematic approach to the health-care ecosystem, with differing goals and objectives suited to the full spectrum of America's trade discussion fora and negotiating venues;

An outline of the program would include -

1. *Institutional change*: Ensure coordination of policy and objectives across agencies and in different negotiating fora. Consistent with the statutory organization of trade policy in general, the logical way to achieve this would be the creation of a new negotiating position – an Ambassador-level Special Negotiator for Health Industries– at the U.S. Trade Representative Office, able to assemble a team with detailees from the Commerce Department, Health and Human Services Department, the U.S. Agency for International Development, the Federal Communications Commission, and other appropriate agencies. The U.S. Trade Representative and Commerce, in our view, should remain separate entities with the USTR leading negotiations and Commerce leading export promotion.

2. *Data collection*: Provide a 'baseline' of data by directing the Commerce Department's Bureau of Economic Analysis to collect data on health-service sector exports and imports, to ensure that negotiators can set the correct priorities and evaluate their work based on facts. This would include revenues from intellectual property royalties and licensing, from care and diagnosis provided by hospitals, from contract research and development, health insurance and IT, and from telemedicine. These should be available by country as well as by industry.

This data should be backed by two studies of future market opportunities. One, done by the International Trade Commission (ITC), would be a formal study of the global health care market, changes underway in developed-country health systems, and the types of health services and goods most likely to be in demand in large developing countries. The other, done by the DOC's Foreign Commercial Services, would be an analysis of the trade and investment restrictions facing U.S. industry in major markets.

3. *Negotiating goals*: Negotiations should serve a larger vision, of a global health market of the next decade, in which innovative American manufacturers, providers, professionals and IT and financial services can serve both large established economies and provide care for rapidly growing developing countries. To achieve this vision, we will need a coherent set of health-ecosystem goals sought across the administration's major trade initiatives. This would include the WTO and the Doha Round (or a successor agenda); ongoing free-trade area negotiations

beginning with the Trans-Pacific Partnership; developed-world discussion groups including the Transatlantic Economic Council, the U.S.-Japan Dialogue, and the Beyond the Border Initiative with Canada; regional dialogues including APEC, the Summits of the Americas, and the annual AGOA forums; the U.S.-China Strategic and Economic Dialogue and the U.S.-India Economic Dialogue; U.S.-Israel trade dialogues and other fora such as bilateral Trade and Investment Framework Agreements and commercial dialogues. These should include six major types of negotiating goals, complemented with greater export-promotion efforts for health-ecosystem goods and services – particularly for smaller and medium-sized manufacturers and services providers, which are often less able to find information about potential foreign markets – through the Commerce Department, the Trade Development Agency, USAID, and other appropriate agencies:

- *Zero-tariff and zero-NTB policies for medicines and medical devices* for all major economies, through any WTO negotiations underway in the next decade, the thirty ongoing WTO accession agreements, all FTAs or regional trade agreements, and through commitments in the U.S.-China Strategic and Economic Dialogue and the U.S.-India Trade Policy Forum.
- *Transparent, accountable and nondiscriminatory regulatory systems* for approval of new medicines and devices and reimbursements, to include avenues for appeal to a clear higher authority when appropriate. Less-developed country partners will also often benefit from capacity-building programs associated with trade agreements.
- *Competitive government procurement systems and disciplines on state-owned enterprises*, to ensure access and avert discriminatory purchasing requirements in health-ecosystem manufacturing, medicines and medical devices, provision of health IT systems, and other services.
- *Services-sector goals applied to payers such as insurers, providers such as hospitals, IT providers, professionals and others as appropriate*. Providers and insurers should be able to establish branches and operations abroad with no artificial limits on their equity ownership (in the same way that the U.S. does not impose such arbitrary ownership restrictions on foreign health care companies doing business in the United States). They should be able to compete fairly with local companies on a level playing field in terms of taxes, regulatory provisions and licenses, and all other non-discriminatory legal and financial requirements. They should where appropriate be able to provide services from a base in the United States, or travel when necessary, as in the case of doctors or hospital-managers consulting abroad.
- *Robust protection of intellectual property rights* along the lines of protections in the Korea-U.S. Free Trade Agreement, and consistent with those in American law, ensuring that intellectual property theft does not vitiate access to markets and that incentives for research remain strong.

- *Electronic Commerce/Telemedicine*: Special focus for telemedicine, enabling providers to export services across borders consistent with national or professional standards set for providing care, based on quality of care.
 - *Efficient and fair standards-setting*, to ensure that products are compatible across borders, enable innovative American products to be used world-wide, and help developing-world health ministries define the needs of their populations.
4. *Venues*: These goals should be pursued at appropriate levels in all of the following negotiating fora and discussion venues:
- i. *WTO and Doha Round* – Here, as former U.S. Trade Representative Susan Schwab has suggested, American negotiators should set the broad goal of “a multiparty accord for a package that includes pharmaceuticals, medical equipment and health-care services, designed to reduce the cost of covering health care,” involving the major WTO members and signed either within a rapidly concluded Doha Round or through an alternative sectoral mechanism.
 - ii. *Asia-Pacific Economic Cooperation (APEC), AGOA Forum, Summits of the Americas* – APEC and similar regional meetings have a special value in addressing regulatory transparency, trans-border investment, cooperative research, medical tourism and other topics.
 - iii. *Trans-Pacific Partnership and other FTA negotiations* – FTAs, meant to be comprehensive agreements that can go beyond WTO commitments, should seek an in-depth, comprehensive set of commitments to open markets in health services, regulatory systems, technical standards and fully open markets for all health manufactures.
 - iv. *China Strategic and Economic Dialogue, U.S.-India Economic Dialogue, other developing-country bilateral fora* – In these large bilateral fora, U.S. goals can include selective reduction of goods trade barriers, regulatory transparency and rights of appeal, rights of establishment and trading rights for hospitals and other providers, encouragement of telemedicine, clinical trials, m-Health and means of providing high-quality care to rural areas.
 - v. *Trans-Atlantic Economic Council, U.S.-Japan Dialogue, Beyond the Border, U.S.-Israel dialogues including modernization of US-Israel FTA, and other bilateral country dialogues* – These dialogues with developed-country partners can focus on regulatory approval processes, cooperative standards-setting, deeper collaboration between public-sector laboratories, cross-border rights of establishment for clinics and hospitals, telemedicine and e-health options, and other issues that affect market access for goods and services in the health-care ecosystem.
 - vi. *World Health Organization* – The WHO, though not a negotiating forum, has an important role in standards-setting for medical devices. In this capacity it can be an

important forum in which to build awareness of new and low-cost medical devices that could benefit lower-income countries.

IV. CONCLUSION AND OPPORTUNITY

This is a demanding strategy which requires a sustained commitment from the U.S. government for much of this decade and beyond. It is a large effort – but it suits a world with large needs, whether for growth and job creation in the United States, for the changing health landscapes of the developed world, or for improved health outcomes in the world’s poorer and middle-income nations.

The United States needs a durable source of growth, based on investment, innovation, real-economy production and exports. The health ecosystem can provide it, promising steady creation of high-wage jobs for highly-educated scientists and professionals, managers and administrators, and blue-collar workers alike – and helping to preserve America’s century-old place as the world’s most advanced, productive and powerful economy.

The world’s demand for high-quality care is surging as the global middle class grows, and as new technologies open up the possibility of regular basic care, safe pregnancies and childhoods, and efficient treatments during illness for a billion low-income and rural people. America’s health eco-system – by virtue of its sheer size, its innovativeness and technical excellence, and its demonstrated record as a provider of care to the ethnically and economically diverse American population – is likely the only health system able to meet this demand at scale.

This is, in sum, a rare moment at which the strengths of a leading part of the American economy mesh with the nation’s hopes for a durable recovery and a lasting source of growth, and with the hopes of billions for better health and better lives. Few policy opportunities will do as much for these hopes as the health ecosystem trade strategy we have outlined in this paper. It is an extraordinary opportunity which America must not miss.

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⁴ Bureau of Labor Statistics, Job Openings and Labor Turnover Survey, <http://stats.bls.gov/data/>

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