

*Universities Allied for Essential Medicines presents...*

# Global Access to Medicines Month



*Our Labs. Our Drugs. Our Responsibility.*

**April 2010**

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## INTRODUCTION TO GLOBAL ACCESS TO MEDICINES MONTH (GAMM)

During the month of April, join students, faculty, and researchers at schools across the country for Global Access to Medicine Month by demanding that life-saving drugs and discovered in your campus laboratories be made available in poor countries and that universities stay true to their non-profit missions in supporting positive legislation – no industry profits.

### PEOPLE ARE DYING BECAUSE THEY CANNOT ACCESS EXISTING MEDICINES

The World Health Organization estimates that ten million people die every year who could be saved by existing drugs but are simply too poor to afford them. Many others barriers to access to affordable genetic tests and medicines are created by universities fighting on the side of industry rather than patients.

#### THE PROMISE: YALE AND STAVUDINE

Yale University created one of the first AIDS drugs, a molecule known as stavudine. Within a few years of its release, stavudine had revolutionized AIDS treatment, and helped change HIV/AIDS from a rapid death sentence to a manageable – if difficult – condition.

But – as the drug’s discoverer wrote in the editorial pages of the *New York Times* – it soon became clear that stavudine “was not reaching millions of desperately suffering people because they lacked the money to purchase it.”

Working with students on campus, *Médecins Sans Frontières* (MSF) urged Yale, as the patent-holder, to help increase access to the urgently needed drug. MSF’s request exploded into a student campaign that gave birth to Universities Allied for Essential Medicines.

Under pressure, Yale and Bristol-Myers Squibb jointly announced that they would allow generic manufacturers of Stavudine to compete in certain markets, thus **lowering the price of the drug from \$1600 per patient per year to just \$55 – a 96% reduction.**

#### UNIVERSITIES CAN CHANGE THIS

Because many life-saving drugs are developed in campus laboratories, universities wield substantial leverage when they license their drugs to pharmaceutical companies.

Our proposal is simple: **Every university-developed drug, vaccine, or medical diagnostic should be licensed with a concrete, effective, and transparent strategy to make affordable versions available in poor countries for essential medical care.**

#### WHAT WE DO

**Universities Allied for Essential Medicines (UAEM)** helps students campaign at academic institutions around the world to make certain that medicines discovered on our campuses are made affordable and accessible to patients in developing countries. We also work to play a positive role in creating legislation that brings better access to healthcare to patients in our home countries and around the world. This legislation at the national level can have profound effects on access to medicines at the global level. We believe universities should work for the public interest by designing

policies and taking public positions that push for better healthcare for patients. Too often, universities have failed to live up to this expectation, both by failing to responsibly manage the essential medicines emerging from their labs, and by taking public positions that favor the interests of the pharmaceutical industry over the interests of patients.



In order to hold universities accountable, UAEM calls on students to participate in a Global Access to Medicines Month of action in solidarity with other chapters around the world (formerly Global Access to Medicines Day). We would like to extend an invitation for your chapter to participate this April in a concerted action designed to encourage our universities to support global access to medicines.

## TAKE ACTION!

Join students, faculty, and researchers at top research institutions in the U.S, Canada and Europe by demanding that lifesaving drugs developed in your campus laboratories be made available in poor countries and that universities stay true to their non-profit mission.

In North America, a sample set of actions could be:

- Table to collect signatures asking your university leadership to stand up for access rather than industry profits
- Write to those at your school who are members of AUTM regarding gene patenting, asking for their support
- Write to your university president asking him/her to fight for affordable medicines

Other potential activities include:

### - Learn

- Screen a movie: show the film *Pills, Profits Protest* on your campus to teach your fellow students about the barriers to ensuring access to medicines
- Organize or attend a workshop on intellectual property, trade agreements and access to medicines.

### - Build

- Host a sign-on for the Philadelphia Consensus Statement (PCS) or related statement to add your campus' voices to the thousands already calling for universities to play their role in ensuring access to medicines. Log your new PCS signatures on <http://www.essentialmedicine.org/cs> to be counted as more voices calling for change.

### - Act

- Meet with your university administrators to let them know the actions they should be taking to improve access to medicines.
- Hold a rally to draw the attention of university administrators and students alike.

## Some Suggested Rallying Points

### I. International Action

Global Access Licensing: This year, a number of major universities including Harvard, Yale, Penn, Duke, UBC, and the National Institutes of Health, in response to UAEM campaigning, adopted a policy statement committing them to ensuring low-cost access to medicines discovered on those campuses for patients in developing countries. This statement represents a non-controversial partial step on the road to achieving better access to university technology. In spite of its endorsement by leading research institutions, many of our universities have declined to sign on to this statement. **Every university must take progressive action and adopt effective global access licensing policies.** Endorsing the statement is a simple first step; we believe universities can and should go further. See if your campus has endorsed the *Statement of Principles and Strategies* at [www.autm.net/endorse](http://www.autm.net/endorse), read



UAEM's critique of the statement and suggestions on how to move access policies even further along.

## II. North American Action

Generic Biologics. In the recent debate over healthcare reform in the United States, universities have stood with pharmaceutical and biotechnology industry groups in fighting for legislation that will hurt patients by keeping the costs of new medicines high. The United States Congress has very recently adopted long-overdue reforms to allow generic production of biologics, drugs derived from living cells. Universities have supported a fake generic pathway that would use lengthy new patent-like intellectual property provisions to prevent most generic biologics from reaching patients in need. Big Pharma has already signaled that when it wins the biologics battle in the US, it will lobby hard to expand these anti-competitive protections to all new drugs, and use U.S. clout in trade negotiations to push for similar legislation around the world. The Association of American Universities (AAU), has been a critical voice in lobbying for this harmful bill, and many of our universities in the United States and Canada are members of AAU. **Universities must retract their endorsement of federal legislation that prevent affordable access to generic biologics and work to ensure these measures are expanded.** See if your university is an AAU member at [www.aau.edu](http://www.aau.edu) and learn more about generic biologics at [www.affordablemedsnow.org](http://www.affordablemedsnow.org).

Gene Patenting. Excessive patenting of genes by universities and others has led to blockages in life-saving research and put high costs on using our own genes to improve our health. Recently, an expert federal panel made recommendations to the Secretary of Health and Human Services to curb abusive gene patenting. In response, a trade association of university administrators, the Association of University Technology Managers, (AUTM) publicly fought the panel's recommendations and argued in favor of maintaining the abusive practices. This approach puts industry profits in front of the interests of researchers and patients. **Universities must retract their opposition to the recommendations given to the Secretary of Health and Human Services that work to improve patient access to essential diagnostic services.** Read more at: [www.essentialmedicine.org](http://www.essentialmedicine.org).

## III. Canadian Action

Canada's Access to Medicines Regime (CAMR): CAMR is a compulsory licensing mechanism first introduced in 2004 as part of the Government of Canada's broader strategy to assist developing and least-developed countries in obtaining lower-cost medicines for diseases that are endemic to those populations. It allows Canada to export drugs to countries that need them on a case-by-case, drug-by-drug and country-by-country basis. Bill C-393 is a proposed amendment to simplify CAMR that seeks to remove several legal, administrative and economic barriers and to include legal flexibilities. Bill C-393 has recently passed its second reading in the Canadian House of Commons and is currently scheduled for review by the Standing Committee on Industry, Science and Technology as early as April 2010. **Students in Canada must continue to pressure their politicians to support CAMR reform.** Read more on the issue at [www.essentialmedicine.org/projects/legislation/canada](http://www.essentialmedicine.org/projects/legislation/canada) and [www.aidslaw.ca/camr](http://www.aidslaw.ca/camr).

## IV. European Action

In addition to participating in the Global Access Licensing campaign, there will be additional support for the coordinated chapters in the United Kingdom and Germany later in the

## UNIVERSITIES ALLIED FOR ESSENTIAL MEDICINES

Global Access to Medicines Month – April 2010 [www.essentialmedicine.org/action](http://www.essentialmedicine.org/action)

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month of April. Updated information will be posted at [www.essentialmedicine.org/action](http://www.essentialmedicine.org/action). All chapters are encouraged to take action on global access licensing at their campuses and **use the collective voice of students around the world calling on universities to take progressive action and adopt effective global access licensing policies.** There is significant momentum moving forward with more and more universities recognizing their obligation to ensure that university research is managed in a way that ensures global access to the essential medicines created in our labs. Now is the time to take action.

Overall, the issues above demonstrate a troubling lack of independence of our universities from pharmaceutical and biotechnology companies. Universities often play a critical role in national and international debates over healthcare, because they are trusted to act in the public interest. As members of the university community, we must work to ensure that trust is not abused by taking a position that favors profits over the public interest. Our Global Access to Medicines Month seeks to hold universities accountable to their non-profit mission and dedication to the public good. The annual spring UAEM action is a fantastic and exciting rallying point for students across the globe to draw attention to the role of universities and access to medicines. We hope your chapter can participate, please go to [www.essentialmedicine.org/action](http://www.essentialmedicine.org/action) to learn more about the issues, how your chapter can take action, and to register your event.

Thank you for your hard work and dedication to UAEM's mission and vision. For more information on Global Access to Medicines Month, please contact your appropriate chapter outreach coordinator whose contact information can be found at [www.essentialmedicine.org/chapters/outreach-coordinators](http://www.essentialmedicine.org/chapters/outreach-coordinators).

-UAEM Coordinating Committee



## GLOBAL ACCESS LICENSING

- The core of our proposals is simple: When a university licenses a promising new drug candidate to a pharmaceutical company, it should require that the company allow the drug to be made available in poor countries at the lowest possible cost.

### *Why universities?*

- Universities have a critical role to play in increasing access to essential medicines around the world. As major contributors to drug development, universities are uniquely positioned to influence the way lifesaving medical technologies are developed and deployed.
- Universities own patent rights in key pharmaceuticals to treat HIV/AIDS, cancer, hepatitis B, and countless other diseases.
- A U.S. Senate report in 2000 found that 15 of the 21 drugs with the greatest therapeutic impact were developed using federally funded research, most of which occurs at universities.

### *Global Access Licensing Framework:*

- In 2009, UAEM developed the Global Access Licensing Framework (Framework), which outlines the essential features that any university should include when creating a licensing policy that would ensure generic provision of university-developed biomedical innovations in low- and middle-income countries.
- This document was created in response to the specific language put forth in the Equitable Access License (EAL) that UAEM had previously lobbied for. The GALF provides each technology transfer office with sufficient flexibility to develop its own unique global access policy while guaranteeing that the essential provisions of the EAL are being included. The Framework is available here: [www.essentialmedicine.org/action/resources](http://www.essentialmedicine.org/action/resources).

### *Recent Developments:*

- On November 9<sup>th</sup>, 2009, a collection of 6 universities and the Association of University Technology Managers (AUTM) released the *Statement of Principles and Strategies for the Equitable Dissemination of Medical Technologies* (“Statement of Principles” or “SPS” for short).
- The Statement of Principles includes a number of important developments, including commitments:
  - to not patent in developing countries
  - to invest in research and development on diseases that impact poor countries
  - to develop public metrics that measure the global health impact of university policies
  - to revisit and revise the Principles document biennially
- The Statement of Principles does not go far enough in important ways:
  - It is unclear whether the SPS will ensure access to medicines for the poor in India, China, and Brazil.
    - \* Over 60% of the world’s poor people live in these countries, and universities cannot be true to their public missions if their policies fail to facilitate low-cost access to medical technologies there
    - \* This ambiguity also leaves unclear the ability of generic manufacturers in these critical countries to produce medicines for countries without manufacturing capacity
  - It does not adequately emphasize the important role that generic competition plays in reducing the price of drugs, and thus enhancing access
  - UAEM will soon be releasing an official response to the SPS, check out [www.essentialmedicine.org/action/resources](http://www.essentialmedicine.org/action/resources) for the document once it is released



## GENE PATENTING AND AUTM

### *Background of the campaign*

- Over the past decade, the department of Health and Human Services has taken an increased interest in gene policy (including patient and clinical access to genetic diagnostic testing)
- A series of genetics task forces were formed, and these groups identified patenting and licensing practices (hereafter, “PLP”) as a priority issue in evaluating access
- During 2006-2008, the Secretary’s Advisory Committee on Genetics, Health, and Society (hereafter, “SACGHS”) performed an in-depth study of PLP and their effects on access
- Spring 2009: SACGHS draft report released for public comments (77 total comments received from academics, patient groups, labs, industry, etc.)
- Summer -fall 2009: incorporation of comments/revisions → final report released 5 Feb 2010 (summary of recommendations below)
- In advance of the final report release, industry leaders (eg, president of BIO) wrote a letter of opposition and held a press conference demonizing the report... AUTM representatives also joined in opposition (president Pradhan co-signed letter; J. Soderstrom spoke at press conf)
- UAEM’s actions to date: wrote to AUTM president on 10 March (no response); wrote to Secretary Sebelius on 17 March and issued a press release condemning AUTM

### *What did the SACGHS report find?*

- Focus is ONLY on PLP related to genetic diagnostic testing (not medicines and other therapeutics)
- Patents provide minimal incentive for discovery and innovation, however it is assumed they are needed for commercial development... case studies indicate that patenting/exclusive licensing is neither *necessary nor sufficient* for development
- Patents are NOT needed for the following: to disclose discoveries, to negotiate test coverage contracts with insurers, or to focus the use of gene tests to diseases for which they are indicated
- Effects of PLP on access to tests
  - o Effects on price: high price usually related to business practices rather than type of PLP
  - o Effects on clinical availability: exclusive rights-holders can and will shut down competing labs (establish monopoly); sole-provider scenario may limit availability of test to clinics and strain capacity (reflected in slow turnaround time for test results)
  - o Effects on patient access: problems usually arise from exclusive licenses...
    1. market-clearing practices eliminate possibility of confirmatory test (“second opinion”), *hindering informed medical decisions*
    2. unwillingness to accept particular insurance plans limits access by many insured patients (not to mention the *uninsured*)
    3. company scruples may eliminate some types of testing for all (eg, University of Utah refuses to test fetal samples)
- Other areas of concern in the current PLP regime
  - o Sole provider schemes may be a barrier to quality improvement (eg, Myriad’s breast cancer test had lots of false negatives with no internal incentive to improve it)
  - o Biggest problem in the future may be in genetic innovation: patent thickets will be inevitable as multiplex and whole-genome tests are developed → not clear whether existing solutions (eg, patent pools) will solve these problems completely
  - o Currently, researchers can be held liable for studying patented genes, and clinicians can be held liable for using genetic tests!



### *What does the report recommend?*

- Conclusion: *there is no clear evidence that gene patents are necessary to stimulate test research and development, and harms to patients outweigh any potential advantages in this regard*
- SACGHS's most favored solution: tailored liability exemptions
  - o Exemption for *anyone who infringes a patent on a gene while making, using, ordering, offering for sale, or selling a genetic test for diagnostic purposes*
  - o Exemption for *those who use patent-protected genes in the pursuit of research*
- These are not out of line with international policy studies (eg, Nuffield Council 2002) and frameworks (eg, Belgian research exemption) and would NOT violate TRIPS
- Other useful points of action (less controversial but probably limited in efficacy):
  - o promote adherence to norms designed to ensure access (eg, NIH policy)
  - o enhance transparency standards in licensing
  - o establish a permanent advisory body in this area/provide expertise to USPTO
  - o ensure equal access (eg, by establishing uniform insurance reimbursement standards)

### *How to deal with industry and AUTM opposition*

- Main types of arguments:
  - o SACGHS recs will undermine American innovation
    - Reality: exemptions are limited to PLP re: gene tests... do not affect therapeutics or any other type of biotech innovations
  - o There are no systemic access problems
    - Reality: this ignores the report's findings, the public comments affirming access problems, and the tacit admission even by dissenting members of SACGHS
  - o The report is biased against industry
    - Reality: evidence in this field is limited, but the problems found demand action; most SACGHS members in fact have worked in/alongside industry
- AUTM's stance on this issue contradicts its prior policy statements (eg, 2007 Stanford Nine Points and 2009 SPS), which endorse:
  - o Limited use of exclusive licensing
  - o Broad access to research tools (which include patented genes)
  - o Limited enforcement of patents, and protection of healthcare providers and researchers from infringement liability
  - o Development of technologies for the public good
- Questions to ask AUTM members: most of the "problem companies" in the SACGHS report had gotten their licenses from universities... so...
  - o Are you really saying there are no problems with the deals you've made? If so, can you justify these deals on any other basis than revenue? (remember that the report found that exclusive licensees were *always* the *last* company to market with a test!)
  - o If the licenses *were* badly done, can you assure us that similar problems won't arise in the future?

Why did you join industry in opposition, rather than propose alternative solutions? (aka the "who's side are you on, anyway?" argument)



## GENERIC BIOLOGICS AND AAU

### *Importance of Biologics*

- Biologics include anything produced in a living cell. These include most new cancer drugs, as well as treatments for Arthritis, MS and many other conditions.
- \$286.5 billion were spent on pharmaceutical drugs in 2007; 40 billion of this was for biologic drugs. About a quarter of new drugs, and half of important new drugs, are biologics.
- Currently 36% of the Medicare part B budget is spent on the top six biologic drugs. These drugs are on average 22 times the cost of traditional chemical drugs and often cost over \$100,000 a year per patient.

### *Financial Savings + Patient Access*

- History shows that market competition along with civic engagement are the only mechanisms to bring down the price of medicines. (Ex: HIV treatment in 2001 cost \$10,000 +, now it is < \$100 per person per year.)
- The United States predicted Hatch-Waxman would save \$1 billion over the first 10 years. In the last decade, we have saved \$734 billion due to this act of legislation.
- Congressional Budget Office (CBO) studies shows that after generic versions of conventional drugs enter the U.S. market, prices fall 40-80%. According to the Federal Trade Commission, biosimilars may lower the costs of biologic drugs by 20-40% and there is reason to believe that the effect may be even greater.
- Conservative estimates have suggested that the US would save \$71 billion over the next 10 years by allowing biosimilars into the market.

### *Problems with Biologics Legislation in Health Care Reform*

- Just enacted health care reform legislation contains two seriously flawed policies that threaten to delay generic entry of biologics into the market.
- Exorbitantly long periods of exclusivity -12 years
  - Traditional drugs receive 5 years of data exclusivity under Hatch-Waxman (1984)
  - The Federal Trade Commission released a major study in July 2009 that recommended zero years of data exclusivity for Biologics.
  - An AARP analysis of time to cost recovery for the top 10 selling biologics in the US showed that all 10 had reached cost recovery within three years of going on the market.
- Evergreening clauses-would extend or renew the 12-year period of exclusivity for cheap and easy tweaks to the drug formulation that could result in perpetual market monopolies.

### *We have already paid for these medications*

- Public money accounts for over 50% of the research and development funding globally. Taxpayers subsidize pharmaceutical advertising to the tune of \$37 billion, and the industry then spends two times what it does on research and development on promotional expenses.

### *Lobbying Disadvantage*

- In 2008, the pharmaceutical industry spent more than \$234 million on federal lobbying; equal to \$125,000 for every hour that Congress was in session. One in five lobbyists hired by the pharmaceutical industry was once a public servant (former Chiefs of Staff, legislative directors, councils/aids, and even members of Congress).



## CANADA'S ACCESS TO MEDICINES REGIME (CAMR) REFORM

### *What is CAMR?*

- Canada's Access to Medicines Regime (CAMR) is a compulsory licensing mechanism first introduced in 2004 and is part of the Government of Canada's broader strategy to assist developing and least-developed countries in obtaining lower-cost medicines for diseases that are endemic to those populations.
- Generic pharmaceutical companies may apply for an export-only compulsory license to manufacture a specific quantity of an on-patent drug for a limited period of two years.
- CAMR is an implementation of the WTO's August 30th Decision—an amendment of the Trade Related Aspects of Intellectual Property Rights (TRIPs) agreement—that allows Member countries to export drugs to countries that need them on a case by case, drug by drug and country by country basis.
- While various countries have now implemented or are in the process of implementing this Decision into domestic legislation, to date Canada is the only country to have issued a compulsory license under this waiver for the export of an antiretroviral (ARV) drug to Rwanda. The negotiation took five years to deliver one drug order to Rwanda and it became apparent to all stakeholders involved that in practice, CAMR was more restrictive than TRIPs.
- Bill C-393 is a proposed amendment to simplify CAMR that seeks to remove several legal, administrative and economic barriers and to include legal flexibilities outlined in the WTO TRIPs Agreement.
- Bill C-393 has recently passed its second reading in the Canadian House of Commons and is currently scheduled for review by the Standing Committee on Industry, Science and Technology as early as April 2010.

### *Take part in the campaign, join the working group!*

- Canadian university students are in a strong position today to increase public awareness of the role of CAMR in the global access to medicines crisis. Though the bill has passed a crucial second vote, it must go through committee review before it can reach a final vote on the floor to become law.
- As the campaign advances forward, we hope to work further with partner organizations and:
  - Continue our letter-writing campaign to Canadian politicians at critical votes
  - Present in person with a written report to the Parliamentary Industry Committee on the necessity of CAMR reform
  - Promote awareness in Canadian campuses and media about compulsory licensing and other solutions for resolving the access gap
- We encourage students to join the UAEM-Canada working group to keep up to date on the latest updates and plans for action.
- Students can join by contacting Kevin Hooi ([Kevin.Hooi@ubc-uaem.org](mailto:Kevin.Hooi@ubc-uaem.org)) and Stephanie Gatto ([Stephanie.Gatto@gmail.com](mailto:Stephanie.Gatto@gmail.com)).
- Students can also learn more about CAMR legislation through the HIV/AIDS Legal Network at [www.aidslaw.ca/camr](http://www.aidslaw.ca/camr)



## HOW TO TAKE ACTION

Here's a list of ideas you can incorporate into your chapter's plan for Global Access to Medicines Month:

- Meet with campus administrators
  - Discuss university involvement in the anti-access positions AAU and AUTM have adopted
- Hold a "teach-in" or similar educational event
  - Educate university community members on:
    - \* the role of universities in the global health crisis
    - \* the increasing "pharmatization" of our campuses
- Organize a panel of speakers to discuss some of the main issues, here are some ideas for participants:
  - Genetics researcher familiar with gene patenting and licensing
  - Science professor who has developed and licensed a drug or diagnostic and support affordable access to it
  - Lawyer familiar with ACLU case challenging the breast/ovarian cancer gene patents
  - Doctor or member of local patient advocacy group to talk about high price of biologics or gene diagnostics
- Stage a rally/protest/demonstration
- Gather signatures on a large poster
- Write a letter to your administration and gather signatures
- Submit a letter to the editor or op-ed

UAEM has tools including t-shirts, stickers and posters that you can order when you register here: [www.essentialmedicine.org/action/register](http://www.essentialmedicine.org/action/register). All of these tools make it very easy to table to collect signatures and raise awareness. Please let us know when your event will be so that we can post it on the website.



## GUIDE TO WRITING AN OPED

Jane Andrews ([janelandrews@gmail.com](mailto:janelandrews@gmail.com)) is our op-ed guru and can help you in both drafting, fact-checking and publishing your op-ed. Please stay in touch with her so that we can be of help along the way and further publicize your op-ed once it is published.

While the information below focuses on writing an op-ed on generic biologics, using the fact sheet included above regarding gene patenting, we'd encourage you to potentially include both issues – bring together a focus on the need for universities to focus on their non-profit missions, not industry profits.

### *Why do it?*

- Often those who cannot afford access to high-priced biologics face life-threatening illness, compounded by the threat of financial ruin. Currently, we are all constituents of universities who are speaking with one voice through the American Association of Universities, to support congressional proposals like one described in detail in this campaign that will impede ready access to affordable generic biologic drugs in the United States. This harmful proposal has now been adopted as part of the healthcare reform bill. Perhaps even more concerning, legislation on intellectual property law written in the United States often gets adopted in other countries soon afterwards, and so this detrimental proposal will likely have global impact shortly.

- We want to alert the students, professors and constituents of our universities, that the American Association of Universities is supporting legislation like this in their name, something that goes against the ethos of a nonprofit institution dedicated to the dissemination of knowledge and social good.

- Whether placed in a major newspaper, or sometimes even better-the school newspaper, the op-ed piece will help mobilize public awareness of the issue. Emailing and posting copies of the op-ed piece to your administration's office is key follow-up.

### *Deciding on the target audience:*

- The most obvious place to submit op-eds would be your school newspaper, however additional local media outlets can be located through the AMSA on-line media guide at <http://www.capwiz.com/ams/dbq/media/>. Plug in your zip code, and scan for local newspapers that come up. Click on any newspaper, and information from contact telephone to opinion page editor's name comes up.

### *Finding the right angle*

- Avoid attacking your University for the AAU's harmful stance on the biologic legislation. A better approach would be to question whether your University is aware of the AAU's legislative actions, and suggest that this morally reprehensible political action be stopped. Universities must demand that the AAU represent their opinions, and support global health rather than the profit-minded interests of corporations.

- List key arguments that you plan to incorporate in your op-ed piece to move the public. You might play up the fiscal irresponsibility of giving away this financial bonanza to the pharmaceutical industry if you like, given that universities should be supporting data-driven policy. Alternately because you are at a university, You have ample room to talk about patient affordability, both nationally and globally. Your universities often have a global health slant, which is huge here.



- Consider a co-author for the op-ed piece. For a regional business journal, having an MBA student or business school professor co-author the piece might enhance its appeal to the target audience. For a local newspaper, the byline should mention if the author is a local resident.
- The list of universities belonging to AAU can be found at <http://www.aau.edu/about/article.asp'sx?id=5476>. Big Pharma receives very low marks in public opinion polls (see summary of recent polls at [PerceptionsofPharma\\_SurveyKeyFindings\\_091109.doc](#)), but striking an anti-Pharma stance can come off as anti-corporate or anti-business and turn off part of the public you're trying to persuade. It is easier to strike a pro-patient, pro-affordability and access stance. (Though as you can see, I struggle with the balance myself.)
- Note the undue influence of Big Pharma over the concerns of consumers.
  - The pharmaceutical and health products industry hired 1,814 lobbyists last year.
  - Since 1998, the industry has spent more than \$1.6 billion on federal lobbying.
  - Last year alone, it spent more than \$234 million—a sum that translates into roughly \$125,000 every hour that Congress is in session.
  - In the first three months of 2009, it spent more than \$66.5 million on these politicking efforts—or about \$1.2 million a day that Congress has been open for business.

[Source: Michael Beckel, “Will \$1.2 Million a Day Convince Congress to Buy Big Pharma’s Rx for Change?” Capital Eye Blog, June 25, 2009. Available from: <http://www.opensecrets.org/news/2009/06/will-12-million-a-day-convince.html>

- Consider framing this as an opportunity for your University to demonstrate its priorities —“Though technology transfer is an important part of University revenue, we trust that Johns Hopkins will prioritize its global health goals and consider the patients both in Maryland and around the world whose access to essential medicines depends on responsible legislation around Biologics.”
- Find university angles for the op-ed piece. For example, you might frame this in terms of your school’s new global health policy, it’s newfound commitment to evidence-based medicine, conflict of interest policies, dedication to community service and community responsibility...

### *Researching the Op-Ed*

- Stay on message. We certainly do not be perceived as against health care reform now that this legislation we are against has been rolled into healthcare reform.
  - We favor health care reform now that would ensure affordable, high quality care for all Americans.
  - We also support innovation for pharmaceutical R&D that delivers products addressing public health priorities with reasonable returns on investment.
  - Biologics, an increasingly important part of medical treatment, cost no more than conventional drugs to produce by PhRMA’s own cited studies.
  - Biologics should be affordable and accessible to those in need, both here and abroad.
  - Extended data exclusivity and evergreening are an unnecessary tax on consumers, putting affordable access at risk and stifling innovation.
- To learn more about the biologics legislation that the AAU supported, feel free to reference the Campaign’s and other fact sheets. The briefings produced by Essential Action on these provisions in the health care reform bills and on evergreening, the Campaign’s orientation Powerpoint and fact sheet, and other resource materials are available. It is always good practice to double check the facts and review original sources.



- Be sure to fact check the evidence you cite. Don't shave or stretch the truth. The facts are on our side. Even though footnotes are not required, you may wish to document carefully your version, so that you can go head-to-head with opponents who might contest your claims.
- Note contradictions in Pharma's arguments. PhRMA and BIO, the industry's trade associations, have pushed for 12 years of data exclusivity and evergreening of biologics while PhRMA's own website (2009 Industry Profile) shows that the R&D costs for conventional drugs and biologics are about the same, that biologics have a higher overall success rate in the R&D pipeline, and that there is little difference in development and approval times between biologics and conventional medicines (97.7 vs. 90.3 months). Yet in contrast to conventional drugs that receive only five years of data exclusivity, these Senate's HELP bill and the House's Energy and Commerce Committee's bill offer 12 years of data exclusivity—seven years of monopoly pricing (not counting evergreening) more for no good reason.
- Cite impartial authority. Unlike the industry-supported studies, the U.S. Federal Trade Commission recommended ZERO years of data exclusivity for biologics. The barriers to generic entry of biologics were sufficiently high that this government agency concluded that no data exclusivity for biologics was warranted.

### *Writing / Editing for Publication*

- Remember that the word limit on an op-ed piece is usually less than 800 words. Check though the guidance governing op-ed pieces from your school newspaper; sometimes you must co-author with a student from your undergrad campus.
- Share your op-ed with others for feedback. Through Jane Andrews ([janelandrews@gmail.com](mailto:janelandrews@gmail.com)), the GAMM is following op-ed pieces. We can help you remain on message, find peers who might fact check and provide feedback on your op-ed, and better target your piece.
- Be sure the byline alludes to UAEM.
- Anticipate the opposition's arguments. Don't leave yourself open to easy rebuttal. Anticipate industry arguments and craft and qualify the wording of your arguments in a way that anticipates likely lines of attack.
- Look over the tip sheets on writing an op-ed piece.
  - [http://www.peterwirth.net/media\\_guide/resources/op-ed\\_pieces.html](http://www.peterwirth.net/media_guide/resources/op-ed_pieces.html)
  - [http://action.aclu.org/site/PageServer?pagename=AP\\_write\\_op\\_ed](http://action.aclu.org/site/PageServer?pagename=AP_write_op_ed)
  - [http://news.duke.edu/duke\\_community/oped.html](http://news.duke.edu/duke_community/oped.html)

### *Multiplying the impact*

- Please be sure to let Jane Andrews know of your impending publication of an op-ed piece. We are tracking these on the Campaign's Google Site.
- When submitting your op-ed, be sure to check on the newspaper's turnaround time for deciding on acceptance of submissions. Know how long the review time for publication is. FOLLOW-UP and be persistent. If it is declined, consider—with feedback and revisions—whether another media outlet might work with some reworking of the angle.
- If not publishable, target parts of the op-ed piece for the blogosphere. It could be posted as an articulate, on-line riposte to an opposition op-ed piece.



*Handling the Follow-up*

- You may well receive emails from those who share or oppose your op-ed position. Be careful in follow-up communications and seek campaign advice before responding. Always be careful and polite in such communications. Most importantly, share in a timely way resources uncovered in this way—organizational contacts, institutional stories or industry data.



SAMPLE LETTER TO AAU MEMBER UNIVERSITY PRESIDENT

Office of the President  
242 Garland Hall  
The Johns Hopkins University  
3400 N. Charles St.  
Baltimore, MD 21218  
Phone: 410-516-8068  
Fax: 410-516-6097  
E-mail: [president@jhu.edu](mailto:president@jhu.edu)

Universities Allied for Essential Medicines  
Johns Hopkins University Chapter  
Baltimore, MD 21205

March 14, 2010

Dear President Daniels,

We students at Johns Hopkins University, members of the School of Arts and Sciences, School of Medicine, and School of Public Health are writing to you today to express our concern about recent actions of the American Association of Universities, a coalition of 62 leading US and Canadian research universities of which Johns Hopkins is a member.

On June 3, 2009, the American Association of Universities endorsed HR 1548, the “Pathway for Biosimilars Act.”<sup>1</sup> This legislation was an attempt to create a regulatory approval pathway for generic versions of biologics, a growing class of medications that make up our pharmaceutical market.

Clearly the processes for regulating and approving production of generic biologics are of paramount importance to the well-being of society. Biologics include lifesaving therapies for cancer, autoimmune diseases, and renal failure. Biologic drugs are currently priced at an average of 22 times the cost of small molecule drugs, make up 20% of the US drug market, and are the fastest growing sector of the pharmaceutical industry.<sup>2,3</sup> Historically, generic medications in the United States have saved the nation significant capital. The 1984 passage of Hatch-Waxman legislation that permitted small molecule generics on the market has allowed the United States to save \$734 billion in the last 10 years.<sup>4</sup> Meanwhile, exorbitant healthcare costs in the United States lead to over 60% of this country’s bankruptcies.<sup>5</sup>

<sup>1</sup> <http://www.aau.edu/WorkArea/DownloadAsset.aspx?id=9016>

<sup>2</sup> *Stimulating Innovation in the Biologics Industry: A Balanced Approach to Marketing Exclusivity*. Issue brief. Kolitkoff, Lawrence J., Sept. 2008. Web.

<sup>3</sup> Schacht, Wendy H., and John R. Thomas. "Follow-On Biologics: Intellectual Property and Innovation Issues." *Congressional research service* RL33901 (2009). Web.

<sup>4</sup> Generic Pharmaceutical Association. *Generic Pharmaceuticals Saved \$734 Billion Over Last Decade*. 7 May 2009. Web. <<http://www.prnewswire.com/mnr/GPhA/38110/>>.

<sup>5</sup> Arnst, Catherine. “Study Links Medical Cost and Personal Bankruptcy.” *BusinessWeek* June 4, 2009. Available at: [http://www.businessweek.com/bwdaily/dnflash/content/jun2009/db2009064\\_66...](http://www.businessweek.com/bwdaily/dnflash/content/jun2009/db2009064_66...)



The biologics legislation, originally sponsored by Representatives Eshoo, Inslee, and Barton and supported by the AAU, which has now been passed as a part of healthcare reform, has resulted in 12 years of data exclusivity being granted to brand-name biologic pharmaceutical products, upending the five year data exclusivity standard established by Hatch-Waxman for small molecule pharmaceuticals. Moreover, a loophole in this legislation permits evergreening, or the renewal of this 12-year market exclusivity period, for minor modifications to existent drugs that has the potential to create perpetual monopolies on biologics. The monopoly protections under this bill will force US taxpayers to forego \$71 billion in potential savings that would have otherwise been realized from generic biologics over the next ten years.<sup>6</sup>

While available opposing legislation would have inserted data exclusivity terms for biologics similar to small molecule drugs and avoided the evergreening problem,<sup>7</sup> the AAU chose to support legislation that will keep pharmaceuticals prices high for consumers, reach beyond our borders to restrict access to lifesaving treatments in developing countries, and contribute to increasing federal costs for biologics as they increase in use. The AAU stood alone with the pharmaceutical lobby and against virtually every consumer group in supporting this bill.

Additionally, a report by the Federal Trade Commission was ordered to provide recommendations on appropriate biosimilars legislation, and the economic analysis conducted suggested that zero years of data exclusivity would be appropriate for brand-name biologic pharmaceuticals due to financial (and other) barriers to entry in the biologics market. In contrast to assertions made by BIO and the AAU, the FTC report concluded that additional data exclusivity was not necessary for continued pharmaceutical innovation.<sup>8</sup>

Universities like Johns Hopkins are non-profit organizations dedicated to the dissemination of knowledge for the public good, and should not be supporting a measure that will restrict access to affordable medicines and likely prevent savings to consumers and the federal government amounting to billions of dollars. UAEM, American Medical Student Association, and Essential Action have communicated with the AAU regarding this bill, and this communication is available on the UAEM website.<sup>9</sup> The AAU's response cited the importance of cost recovery for pharmaceutical companies. Due to factors outlined in detail in the FTC report including the more and varied patents that cover biologic products as compared to small molecule products, as well as the fact that competition by biosimilars will be more akin to competition from originator or brand-name companies than introduction of a generic, insofar as originator companies will likely maintain 70 to 90% of their market share, many independent assessments disagree that additional exclusivity is needed for biologic products.

The AAU's response also asserted that the provisions in the legislation sponsored by Representatives Eshoo, Inslee, and Barton are necessary to ensure continued innovation in the biotechnology sector. As stated in the testimony of Momenta Pharmaceuticals (a company that produces both originator and generic products) to the House of Representatives subcommittee hearing on biologics: "the issue is not whether data exclusivity will trigger substantial R&D investment, but rather what kind of R&D it will promote"<sup>10</sup>. Rather than driving true innovation, these provisions would discourage the development of genuinely novel

<sup>6</sup> Miller, Steve, and Jonah Houts. *Potential Savings of Biogenerics in the United States*. Rep. Express Scripts, Feb. 2007. Web. <[www.express-scripts.com/industryresearch/outcomes/onlinepublications/study/potentialSavingsBiogenericsUS.pdf](http://www.express-scripts.com/industryresearch/outcomes/onlinepublications/study/potentialSavingsBiogenericsUS.pdf)>.

<sup>7</sup> <http://www.govtrack.us/congress/bill.xpd?bill=h111-1427>

<sup>8</sup> Federal Trade Commission (FTC), *Emerging Health Care Issues: Follow-on Biologic Drug Competition*, June 2009.

<sup>9</sup> <http://essentialmedicine.org/projects/legislation/usa>

<sup>10</sup> "Statement of Bruce A. Leicher, Sr. Vice President and General Counsel, Momenta Pharmaceuticals, Inc.," <http://judiciary.house.gov/hearings/pdf/Leicher090714.pdf>.

## UNIVERSITIES ALLIED FOR ESSENTIAL MEDICINES

Global Access to Medicines Month – April 2010 [www.essentialmedicine.org/action](http://www.essentialmedicine.org/action)

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treatments by incentivizing the low risk, high-reward development of small improvements on existing products . Momenta’s testimony concludes that “by extending exclusivity beyond patent life, we put truly new innovative R&D further at risk, which will delay urgently needed efforts to discover cures for so many unmet needs.”

The American Association of Universities and Johns Hopkins University represent pinnacles and watchtowers of academic excellence. Johns Hopkins University in particular has recently prioritized global health, and therefore the AAU’s stance is especially out of line with our interests. Over the past decade, due to generic competition, we’ve seen HIV/AIDS drug prices fall from \$10,000/year for triple therapy to less than \$100/year. For the developing world, maladies from AIDS to cancer may someday respond to biologic treatments that can be suitably used there.

Given that the AAU’s members collectively receive over half their research funds from the federal government, universities should not be cornered into defending a policy that hurts consumers and that will likely have global repercussions for access to medicines around the world. We hope that Johns Hopkins, recognizing the importance of global health to itself and other research universities, encourages the AAU to represent the interests of its university members rather than corporations while taking individual responsibility for what is being done in the name of our university.

Sincerely,

Johns Hopkins Chapter UAEM  
Jane Andrews



SAMPLE LETTER TO AUTM MEMBER/TTO

March 17, 2010

ADDRESS TO YOUR TTO/MEMBER OF AUTM AT YOUR UNIVERSITY – WE CAN HELP YOU TO FIND OUT WHO AT YOUR SCHOOL IS A MEMBER

Technology Transfer Officer  
111 Deer Lake Road, Suite 100  
Deerfield, IL 60015

Dear Mr./Ms. TTO,

On March 17, 2010, Universities Allied for Essential Medicines publicly called on the Association of University Technology Managers to retract its opposition to the gene patenting recommendations recently made to Secretary of Health and Human Services Kathleen Sebelius. As a member of AUTM, we would like to engage you on this issue and ask for your support in securing AUTM's retraction [*while adding your support to implementation of the recommendations*].

On February 5, 2010, the United States Department of Health and Human Services Secretary's Advisory Committee on Genetics, Health and Society (SACGHS) released a report titled *Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests*.<sup>11</sup> The report includes recommendations that address the impact of gene patents and licensing practices on clinical and patient access to genetic diagnostic testing.

On the eve of the release of the SACGHS report, an AUTM leader, jointly with the President of the Biotechnology Industry Organization (BIO) and other members of industry sent a letter to Kathleen Sebelius, Secretary of Health and Human Services, urging her to reject the recommendations outlined in the SACGHS report<sup>12</sup>. On that same day, another representative of AUTM participated in a BIO-sponsored press conference<sup>13</sup>. We believe that neither the letter of opposition nor the press conference fairly addressed the SACGHS report's conclusions and recommendations. Furthermore, we believe AUTM's stance on this issue is in fundamental conflict with its past policies and its role as an organization representing university technology transfer managers who, as members of the non-profit university community, should represent researchers and the public interest. For the reasons outlined below, we are calling on AUTM to retract its opposition to the SACGHS recommendations and reaffirm that it intends to represent the interests of its university constituents on issues of gene patenting and licensing for diagnostic tests.

The SACGHS task force was commissioned to perform an in-depth assessment of whether, and to what degree, gene patenting and licensing practices affect clinical and patient access to genetic diagnostic testing. The resulting comprehensive and scholarly report incorporates a wide body of evidence, including empirical analysis, commissioned case studies, and extensive expert and public consultations. The report's case studies, in particular, were purposefully sampled to examine a broad range of patenting and licensing practices and to understand what these practices are actually accomplishing for patients.

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<sup>11</sup> See the SACGHS final report released Feb 5, 2010. Accessed from [http://oba.od.nih.gov/SACGHS/sacghs\\_documents.html#GHSDOC\\_011](http://oba.od.nih.gov/SACGHS/sacghs_documents.html#GHSDOC_011) on March 3, 2010.

<sup>12</sup> [http://bio.org/ip/genepat/documents/SACGHSsign-onletter2-4-2010final\\_000.pdf](http://bio.org/ip/genepat/documents/SACGHSsign-onletter2-4-2010final_000.pdf). Accessed March 3, 2010.

<sup>13</sup> [http://www.bio.org/podcasts/020410\\_NPC.mp3](http://www.bio.org/podcasts/020410_NPC.mp3). Accessed March 3, 2010.



The report concludes unequivocally that broad gene patent claims and exclusive licensing terms can have adverse effects on the market for genetic diagnostics and on clinical and patient access to genetic testing. SACGHS carefully deliberated a range of policy solutions, and their final recommendations draw directly from the report's conclusions. These recommendations are focused policy reforms tailored to improve patient access to essential diagnostic services while maintaining the aims of the Bayh-Dole Act and the current U.S. regime of intellectual property and life sciences innovation.

It is unfortunate, then, that the content of the opposition letter and press conference in which AUTM members participated grossly misrepresents the conclusions and recommendations of the SACGHS report. Three erroneous claims were made in the letter and media event, namely:

1. *The proposed policy changes will “undermine the foundations of American life sciences innovation,”*<sup>2</sup> by “discourage[ing] investment... undermin[ing] research... and harm[ing] patients.”<sup>5</sup> This is unwarranted speculation and lacks empirical support. What is more problematic, however, is that there is no distinction in this argument between the limited reforms that SACGHS recommends for genetic diagnostics, and the whole system of intellectual property protection and technology transfer which will certainly remain otherwise intact.

2. *There are no access problems in the first place.* It is stated, for example, that the SACGHS report is “based on claims of a crisis... that does not exist,”<sup>2</sup> and that “the Committee found that access is not harmed.”<sup>3</sup> These claims blatantly contradict the findings of the report and the accompanying public comments, including the tacit admission by the Committee's own dissenting voices.<sup>14</sup>

3. *The scientific integrity of the SACGHS task force and expert consultants is questionable.* An AUTM representative proposed that the case studies were “not selected by any objective, fair-minded, or even random basis, but [were] essentially hand-selected, frankly, by folks who had a point of view.”<sup>3</sup> This type of argument precludes any reasonable discussion of scientific evidence and policy solutions. By all accounts, the case studies were purposefully sampled by the commissioned researchers and the SACGHS members to shed light on the intellectual property arena surrounding genetic diagnostic testing. Furthermore, the published committee roster lists a diverse range of experts in the field, including clinicians, researchers, IP law experts and industry representatives. The majority of committee members, including the committee chair, has experience in or has worked alongside industry throughout their careers. In fact, such a diverse group is less likely to have a single-minded, biased “point of view” than a group of opposing industry representatives with a clear financial stake in the status quo.

AUTM has previously signed onto policy statements that contradict its current stance on patenting and licensing for genetic diagnostics. For instance, in the 2007 document *In the Public Interest: Nine Points to Consider in Licensing University Technology*, AUTM endorsed the following principles:<sup>15</sup>

- The right for all universities, non-profit companies, and government organizations to practice university-licensed technologies (Point 1)
- Limited use of exclusive licenses, including shielding healthcare providers and researchers from infringement liability (Point 2)
- Broad access to university research tools (Point 5)

<sup>14</sup> See the SACGHS final report released Feb 5, 2010, lines 3676, 3684, 3698-9, and 3716. Accessed from [http://oba.od.nih.gov/SACGHS/sacghs\\_documents.html#GHSDOC\\_011](http://oba.od.nih.gov/SACGHS/sacghs_documents.html#GHSDOC_011) on March 3, 2010.

<sup>15</sup> See [http://www.autm.net/Nine\\_Points\\_to\\_Consider.htm](http://www.autm.net/Nine_Points_to_Consider.htm). Accessed March 10, 2010.



- Careful use of enforcement actions<sup>16</sup> (Point 6)

Similarly, AUTM signed on to the 2009 *Statement of Principles and Strategies for the Equitable Dissemination of Medical Technologies* (SPS).<sup>17</sup> The SPS affirmed the role of universities and their technology managers in “developing and disseminating [their] technologies for the public good,” and acknowledged that “intellectual property should not become a barrier” to access. Yet when the SACGHS recommended limited liability exemptions to protect researchers and improve patient access, AUTM was opposed.

It is regrettable that AUTM has chosen to solely align itself with a particular industry lobby group rather than also take into account the views and needs of scientists, healthcare providers, and patient groups as presented by an independent government task force – not to mention the non-profit mission of the universities which employ its members.

AUTM has made a commitment to further knowledge and innovation for the public good. We therefore ask you as a member of AUTM to call on the organization to rectify its discordant views on the role of university technology transfer and provide clear support for patenting and licensing gene-based diagnostics in the public interest. A first step would be for AUTM to retract its endorsement of the dissent.

Thank you in advance for your consideration of our concerns. We look forward to your response and for a continuing dialogue with you in this matter.

Sincerely,

X

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<sup>16</sup> We take the spirit of this recommendation to mean that blatantly anticompetitive behavior by licensees, such as has been found with exclusive licensees mentioned in the SACGHS report, is inconsistent with the intent of the university-developed innovations.

<sup>17</sup> See <http://www.autm.net/Content/NavigationMenu/TechTransfer/GlobalHealth/statementofprinciples.pdf>. Accessed March 10, 2010.