Pay for Delay Advocacy Toolkit
October 2010

AMSA PharmFree, UAEM, Prescription Access Litigation, Community Catalyst

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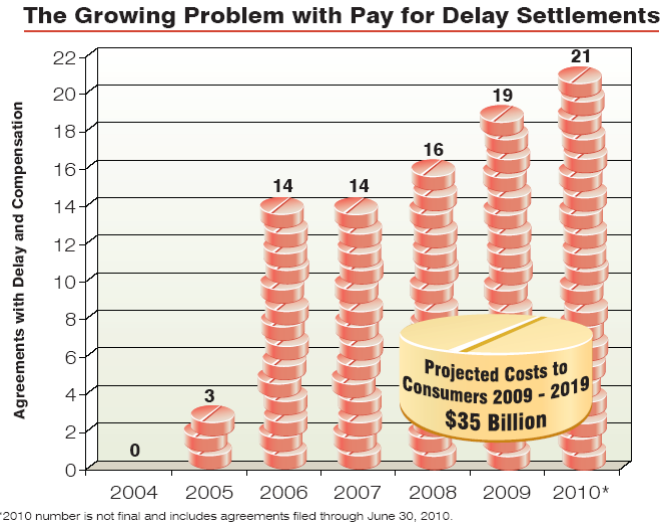
Contents

Pay-for-Delay Fact Sheet

What are Pay-for-Delay settlements?

Pay-for-delay settlements are agreements made during patent litigation cases where a brand-name company offers generic-drug manufacturers cash payments or some other compensation in exchange for a period of delay in the marketing of cheaper (bioequivalent) drugs. The results: Consumers pay the higher prices for these drugs for longer. These types of deals are becoming more common: 14 settlements were made in 2006 and 2007, 16 in 2008, 19 in 2009, and 21 in the first 9 months of 2010. These deals are estimated to cost US consumers $3.5 to $7.5 billion per year.



Source: Federal Trade Commission

Please visit:

www.tinyurl.com/emailpay4delay

to send a message to your Senator and Congressperson in support of the ban on Pay-for-Delay settlements!

Why are these settlements taking place?

Under the Hatch-Waxman Act of 1984, generic-drug companies have an incentive to challenge patents because the first generic to file its application with the Food and Drug Administration (FDA) can obtain 180 days of marketing exclusivity during which it is the only generic allowed on the market.[1] To seek approval for entry before patent expiration, a generic must declare that its product does not infringe the relevant patents or that the relevant patents

[1] By creating the Abbreviated New Drug Application (ANDA), Hatch-Waxman allows approval of generic products through a shorter and less costly route than for innovator drugs. ANDA rules offer four routes for marketing of generic drugs. Three routes--called Paragraph I, Paragraph II, and Paragraph III certifications--apply to ANDA filings that do not involve challenges to patents still protecting brand-name products. Through these routes, more than one generic version can hit the market at the same time, creating a very competitive situation. The fourth route, called Paragraph IV certification, applies when patent protection has not expired but the generic drugmaker claims either that the patent is invalid or that its product does not infringe the patent. Generic drug companies aim to be first to file ANDAs with Paragraph IV certification because the rules make them eligible for a 180-day period of marketing exclusivity. During this period, FDA may not approve other ANDAs for the same product. The exclusivity period motivates generic companies to innovate around patents for brand-name drug products. Hatch-Waxman also allows generic companies to obtain bioequivalency data required for their drug applications before patent expiration. Because of Hatch-Waxman, generic versions hit the market as soon as patent protections on the brand-name product expire, in contrast to the case in many other countries. Before Hatch-Waxman, only 35% of pioneer drugs had generic competition after patents expired; now almost all innovator drugs face such competition.– Adapted from: Chemical and Engineering News. Beyond Hatch-Waxman, Legislative action seeks to close loopholes in U.S. law that delay entry of generics into the market. Volume 80, Number 38. September 2002, available at http://tinyurl.com/hatch-waxman

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are invalid. Typically, brand-name pharmaceutical companies challenge the generic's declaration, and litigation ensues between the brand-name and generic pharmaceutical manufacturers to determine whether the relevant patents are valid or infringed.

For years, the Federal Trade Commission (FTC) enforced federal anti-trust law to prevent possible collusion between generic and brand name drug makers to settle their litigation with a payment in exchange for a delay in bringing the low cost generic drug to market. But in 2005, the courts started to allow these agreements under anti-trust law. Both originator and generic manufacturers favor these Pay-for-Delay settlements because they allow brand name drug prices to stay high and guarantee payout for generic companies. Consumers ultimately lose by missing out on generic prices which may be 60-99% less than brand-name prices.

Why are Pay-for-Delay settlements problematic?

1. Cost – Access to generic drugs has saved over $730 billion dollars in drug costs since 2001, but these pay-for-delay settlements are slowing the availability of generic drugs.[2] The Federal Trade Commission (FTC) released a report in 2010 which showed that patent litigation agreements with compensation on average delayed generic entry for **17 months longer** than agreements without payments.[3] Economists at the FTC conservatively estimate that these deals will cost US consumers **$35 Billion** over the next 10 years.

2. Access to Medicines at Home and Abroad – Protecting brand name drugs that are cost-prohibitive delays access to more affordable treatments for vulnerable populations with limited income in the U.S. and abroad. Domestically, these settlements limit the prescribing choices of physicians and hurt quality of care. Internationally, delayed access to generic drugs can cost thousands of lives. For example, generic competition lowered the cost of a popular first line antiretroviral treatment regimen from $10,000 to under $67 per patient per year.[4] Generic drugs also result in cost savings for global health programs funded by US taxpayers. Between 2005-2008, the US Federal Government saved $320 million through the use of generic procurement in the President's Emergency Plan for AIDS Relief (PEFAR).[5] These cost savings could mean putting more people on life saving medications. This same line of reasoning can be extended to medicines that treat other life-threatening conditions such as cardiovascular disease or bacterial infections. For example, Bayer Corp, maker of the antibiotic Ciprofloxacin, paid three different generic drug competitors a combined $400 million to delay any generic for six and a half years.

3. Innovation – The Hatch-Waxman Act encourages generic companies to challenge weak patents, i.e. those that are likely to be ruled invalid or non-infringed. Reverse payment (aka Pay-for-Delay) settlements allow brand-name companies to continue charging high prices for drugs that are protected by weak patents

"Brand companies are most likely to pay-off a generic competitor when they have not innovated. As defenders of these settlements have conceded, the incentive to pay a generic to abandon its patent challenge is greatest for the weakest patents. As all of us know, competition rather than collusion fosters creativity. The Supreme Court has repeatedly observed that protecting weak patents slows rather than promotes innovation." – Jon Leibowitz, Chairman, FTC

What can I do about these collusive agreements?

[2] AARP, *Rx Watchdog Report*, Vol. 6, Issue 4 (May 2009), available at http://tinyurl.com/AARPGenerics
[3] FTC, Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions, January 2010, available at http://tinyurl.com/FTCPay4DelayReport.
[4] MSF Campaign for Access to Essential Medicines, Untangling the Web of Antiretroviral Price Reductions, July 2010, available at http://utw.msfaccess.org/.
[5] Charles B. Holmes *et al.*, Use of Generic Antiretroviral Agents and Cost Savings in PEPFAR Treatment Programs**,** *JAMA* 2010;304(3):313-320.

The House of Representatives passed legislation in July 2010 which bans Pay-for-Delay settlements and allows the FTC authority to challenge these anti-competitive deals (House Supplemental Appropriations Bill, Chapter 2, Amendment #2, H.R. 4899). Unfortunately, the Senate failed to pass a war bill with similar language on Pay-for-Delay and the House provisions were subsequently dropped. However, a bill similar to the one passed in the House will likely be scheduled for a floor vote once the Senate returns to session after November elections. The relevant bill has passed out of committee and is called **the Senate Financial Services and General Government Appropriations Act, 2011 (S. 3677)**. Specifically, Section 746 of S. 3677 relates to Pay-for-Delay.

Some Senators have threatened to block this important bill.[6] We need your help to make sure Senate Democrats and Republicans will work together to pass this legislation.

"Every day we don't pass this legislation is another day that affordable generics are kept out of the hands of consumers, and another day that taxpayers foot the bill for sky-high prescription drug reimbursements" - Senator Herb Kohl (D-Wisconsin)

To learn more about this issue, or help out with this campaign, please contact Jing Luo (jluo4@uic.edu), Ethan Guillen (ethan.guillen@essentialmedicine.org), or Wells Wilkinson (wwilkinson@communitycatalyst.org).

[6] Bloomberg Businessweek, Republicans Seek to Derail Plans Restricting Drug Company Deals, September 28, 2010, available at http://tinyurl.com/republicansopposeban.

Website and Email Petition

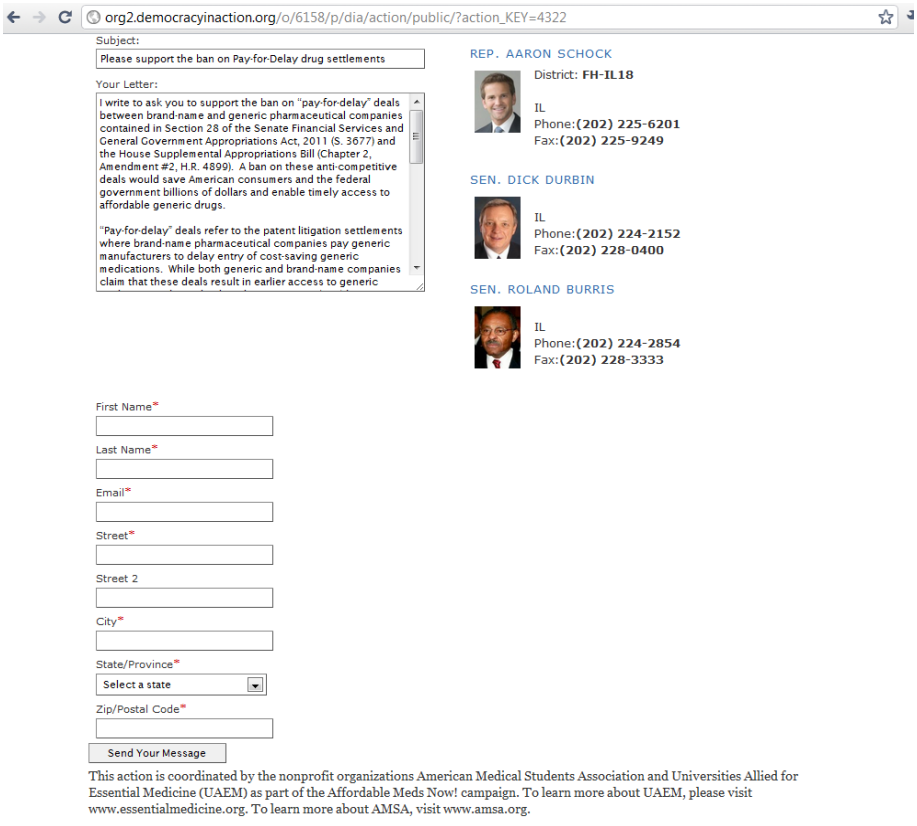
Description of Website

It is anticipated that the majority of our advocacy efforts will be directed through students, residents, staff colleagues and faculty members who are interested in taking a few minutes out of their busy days in order to support this legislation. Thus we aim to direct them to a user-friendly website which will generate a pre-written letter to be emailed to their Senators and Representatives. For this to work, the user only needs to input their name and address (including zip code).

www.tinyurl.com/emailpay4delay

Appearance of Website

On the initial page, users will be asked to input their zip code. After clicking submit, they will be taken to a screen that looks like this:



After sending the message, users will be automatically directed to a webpage where they can input email addresses of friends or other contacts in order to magnify his or her impact.

Classroom / On-campus Sign-up Sheet

We recognize that there may be circumstances in which an electronic sign-on letter may not be the easiest or most practical tool of advocacy.

For example, one could imagine a scenario in which an advocate could give a quick speech about this issue in front of a lecture hall or classroom. Afterwards, he or she would pass out a sign-on / permission sheet (see next two pages) in which people could sign on their support for a ban on Pay-for-Delay drug settlements. All they would have to provide is their name and address (including zip code).

The next two pages of this toolkit represent the FRONT and BACK pages of such a sign-on sheet. Please use it to collect signatures in classrooms, in the hallways / common areas, on bulletin boards, etc...

Recommended Steps:

1) Give a short statement explaining the importance of this issue (see Fact Sheet above), and explain that you are there to collect signatures from people who are interested in supporting this cause.

2) Ask signatories to fill in their complete addresses (including zip code).

3) After you have collected the signatures, please log on to the website (www.tinyurl.com/emailpay4delay) to input each persons information in order to send messages to policymakers in Congress (THIS IS THE MOST IMPORTANT STEP!)

4) Send us a short message by emailing jluo4@uic.edu, to let us know what you did and how many signatures you collected!

5) Please keep the forms somewhere safe for several weeks after inputting them online in case we are ever asked to provide evidence that we have collected actual signatures from real people.

Email Congress for Affordable Generics Now!

Subject: Support legislation banning "Pay-for-Delay" patent litigation settlements

Dear Legislator:

I write to ask you to support the ban on "pay-for-delay" deals between brand-name and generic pharmaceutical companies contained in Section 746 of the Senate Financial Services and General Government Appropriations Act, 2011 (S. 3677) and passed previously in two House bills.. A ban on these anti-competitive deals would save American consumers and the federal government billions of dollars and enable timely access to affordable generic drugs.

"Pay-for-delay" deals refer to patent litigation settlements where brand-name pharmaceutical companies pay generic manufacturers to delay entry of cost-saving generic medications. While both generic and brand-name companies claim that these deals result in earlier access to generic medications, the Federal Trade Commission (FTC) has completed analysis which shows that these deals delay cost-saving generic drugs by an average of 17 months. As a result, the FTC and CBO estimate that these deals will cost American consumers $35 billion over 10 years, including $2.4 billion in increased costs to the federal government.

These types of deals have become increasingly common: the number of "Pay-for-Delay" settlements rose from only three in 2005 to 19 last year and 21 during the first nine months of 2010.

Fortunately the House has twice passed a Pay-For-Delay Ban and the Senate Financial Services and General Government Appropriations Act, 2011 (S. 3677) also contains provisions that would ban this harmful practice. But these provisions continue to be subject to attack from brand-name and generic pharmaceutical lobbyists.

In this time of increasing federal deficits and financial hardship for many Americans, I urge you to support the ban on "Pay-for-Delay" deals, thus saving Americans billions of dollars in increased healthcare costs and ensuring affordable and timely access to medicines.

Sincerely,

(Your name here)

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Flip over to send this letter to up to six members of Congress!

I have reviewed the email template on the reverse side making the case for affordable generic drugs and against "Pay-for-Delay" patent litigation settlements. Using my contact information below, please send out this email on my behalf to my Senators, Representative, and President of the United States. Note: Please print clearly, and remember to include your full address (including zip code)!

Name	**Campus Address** (Street, Building/Apt #, City, State, Zip Code)	**Phone**	**Email Address**	**Permanent Address**	**Email Update (Y/N)***	**Signature**

* Would you like to receive updates via text or email about the AffordableMedsNow.org campaign?

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District Lobbying Visit

A face-to-face visit at the district office of your Senator or Congressperson serves as a real and personal reminder to that constituents care about this issue. Furthermore, it can be a great opportunity to meet and educate district level staff and legislative aides. Visiting and speaking with our representatives can also build strong relationships for future visits and advance other policy goals. Members of Congress and staff are always happy to see health professional students interested in these issues because we represent non-paid, volunteer lobbyists who are interested in patients and the public good.

To Prepare

- Find your Senator or Representative's office number through the Legislative Action Center (www.capwiz.com/ams/dbq/officials/) and **CALL** to schedule an appointment:

  a) Indicate that you represent a group of university or medical students from XXX, and as constituents, would like to pay a visit to see Senator/Congressperson or their staff, particularly the person working on health care reform issues;

  b) Offer a rough estimate, if possible, of the number of those who might attend, particularly voting constituents (if there are student leaders among them, you might mention some of their titles, e.g., AMSA Chapter president);

  c) Give the topic that you would like to discuss with the Congressional office (the 20 second version), that is, Pay-for-Delay drug settlements and earlier access to affordable generic medicines for our patients.

  d) Ask for available windows of time when a meeting with the staffer may be possible and provide your contact information (mobile phone and email, but note the former only may be accessible).

  If in DC, plan multiple visits, particularly to offices where you have a home constituent.

- Prior to the visit, preview materials found in the Fact Sheet (above). Anticipate questions that may arise. Be prepared to answer such questions with evidence. Draft up your own list of Talking Points. Print out and bring multiple copies of the "leave-behind" Fact Sheet (see next page) to leave with office staff.

- Do your homework regarding your Senator or Congressperson's record. How did they vote on healthcare reform? Have they championed health access for the poor? How do they expressed concerns about Industry giveaways? Do they support specific disease research?

- Confirm your appointment one week before the date.

Lobby Day

- Arrange for a meeting point (such as lobby in front of student union) and a time which will give you plenty of time to brief those students who are coming along with you to the visit. Divide up talking points between those who are making the visit. It is always good to share personal stories or patient experiences related to the cost-prohibitive nature of brand-name drugs or the benefits that patients have experienced as a result of generic drugs.

- Ask everyone coming to dress professionally (wear your white coats).

- Don't be late to your visit. Ask everyone to turn off cell phones.

- Everyone in the group should introduce themselves and state briefly why they are interested in this issue.

- Be courteous and avoid partisanship.

- At the end of your visit, ask directly but politely whether the Senator or Congressperson would be interested in supporting or co-sponsoring a bill which would ban Pay-for-Delay settlements. Make sure they remember the relevant bill number (S. 3677). If they say they can't give you an answer right away, ask when they would be able to give you an answer or how they pan to follow up with you.

- Make sure to ask for the business card or take down the contact information of the person you spoke with. Leave them your contact information too! Take a group picture if you have a camera do document the day.

- Leave a fact sheet (one is provided on the next two pages).

- Thank your hosts for their visit.

After the Visit

- Meet briefly to discuss how things went. What went well? What issues could benefit from follow-up, especially with campaign organizers?

- Write a thank you letter as soon as it's over and send it out.

- **PLEASE PLEASE PLEASE** send an email at jluo4@uic.edu and ethan.guillen@essentialmedicine.org to let us know how it went. Please include the following information: district office that you visited, who you spoke with, date of the visit, how many people were in your group, and what the staff person told you regarding what the Senator or Congressperson thinks about this issue. Please also send us a picture if you took one!

FACT SHEET

Ban 'Pay- For- Delay' Collusion to Promote Drug Savings and Access

Generic drugs have saved consumers and federal programs $734 billion

Generic drugs compete with brand names in the marketplace and have saved $734 billion in the past 10 years.[i] The Hatch-Waxman Act of 1984[ii] safely sped up the approval process for generics and thereby helped increase generic drug use from just 12 percent[iii] in 1984 to 70 percent today. Since generic drugs cost 60 to 90 percent less than the brand name drugs they replicate, this has become the most important tool for reducing our ever-rising drugs costs.

The Problem: Drug industry sweetheart deals block competition and prevent higher savings and access through generic drugs

Brand-name drug makers have routinely tried to delay generic rivals with patent infringement lawsuits. But as a result of legal decisions in 2005, brand-name drug makers have paid generic rivals multi-million dollar 'sweetheart deals' to settle these questionable lawsuits. These settlement amounts are far more lucrative than the slim profit margin on a generic drug, and they guarantee the brand-name drug company continued profits without competition from any generic.

For example, Bayer Corp, maker of the antibiotic drug Cipro, paid three different generic drug competitors a combined $400 million to delay any generic for six and a half years. In order to ensure that our health system remains affordable, healthy competition cannot be undermined by industry collusion that limits consumer choices and undermines patient care.

"Pay-for-delay" deals shield $29 billion in yearly drug spending from competition

Two recent reports by the FTC have revealed how costly these settlements are to government programs, consumers, and insurers. A January 2010 FTC report revealed that nearly $20 billion dollars in current annual spending on brand-name drugs is unfairly protected from competition by the 63 settlements then in effect.[iv] A subsequent July report[v] updated this information, noting that a record number of new pay-for-delay settlements – 21 in FY2010 – insulate another $9 billion in brand-name drug sales from competition. January's report revealed that these sweetheart deals delay generics by an average of 17 months. But as the drug industry continues to maneuver the FTC's legal challenges into the industry-friendly 4th and 11th Circuit courts, longer, more costly delays are nearly certain. The delays prevent the 60-90 percent cost savings that lower-priced generic drugs allow, while also undermining patient care.

The Solution: Provide FTC authority to challenge anti-competitive pay-for-delay deals and increase access to generics

Generics should be allowed to come to the market as soon as possible. A ban on pay-for-delay settlements will prevent drug companies from unfairly colluding to keep generics off the market.

The Senate Financial Services and General Government Appropriations Act of 2010 (S. 3677)[vi] provides the FTC with needed authority to protect consumers health market competition.

Pay-for-delay ban to save consumers, health plans billions

The Congressional Budget Office has estimated, conservatively, that a ban would save the federal government $2.4 billion on prescription drug costs over the next decade.[vii] The FTC, which is able to review these agreements filed under seal, estimates that the savings to consumers and our health system overall would be $3.5 billion or more per year.[viii] Other experts predict even more significant savings of $12 billion per year are likely.[ix]

Access to generics drugs improves quality of care

The American Medical Association recently condemned the role these pay-for-delay settlements play in preventing affordable treatment, which can result in no treatment at all in vulnerable populations, or patients on fixed or limited incomes.

Support for a ban on pay-for-delay settlements

President Obama has consistently supported a ban on these anti-competitive deals between drug makers. This policy has been supported by the AMA, AARP, the FTC, the Attorneys-General in 34 states, and numerous consumer, labor, and patient advocacy groups.[x]

For more information: Contact Wells Wilkinson, Staff Attorney, Community Catalyst 617-275-2822 or wwilkinson@communitycatalyst.org

[i] AARP, *Rx Watchdog Report*, Vol. 6, Issue 4 (May 2009), *available at* http://assets.aarp.org/www.aarp.org_/cs/health/205256rxwatchdogmay09.pdf. last accessed 9/10/2010.

[ii] Under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly know as the Hatch-Waxman Act, a generic drug company can use the safety studies of the original drug. The Act also polices against bad drug patents by allowing a generic to be brought to market if the drug's patent is invalid or would not be infringed. According to a 2002 FTC study, generic manufacturers won two-thirds of the patent disputes when litigated in court.

[iii] Food and Drug Administration, Protecting America's Health Through Human Drugs: Greater Access to Generic Drugs (Jan. 2006), available at http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143545.htm. last accessed 9/19/2010.

[iv] FTC, Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions, January 2010, available at http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf, last accessed 9/10/2010).

[v] Oversight of the Federal Trade Commission Bureau of Competition and the Department of Justice Antitrust Division: Before the Unites States House of Representatives Committee on the Judiciary Subcommittee on Courts and Competition Policy, 11th Cong. 2d Sess. (July 27, 2010)(Statement of Jon Leibowitz, Chairman of the Federal Trade Commission). Available at: http://www.ftc.gov/os/testimony/100727antitrustoversight.pdf, last accessed 9/10/2010.

[vi] S. 3677 PCS, The Financial Services and General Government Appropriations Act, 111th Cong, § 746, at 158 (2011).

[vii] CBO, "S. 369: Preserve Access to Affordable Generics Act (Updated Table)", June 16, 2010, available at http://www.cbo.gov/ftpdocs/115xx/doc11582/S369_updated_table.pdf, last accessed 9/10/2010 (revising their earlier January 2010 analysis to reflect the passage of health care reform legislation and to extend the estimates to 2020).

[viii] Jon Leibowitz, Chairman, FTC, speech, "Pay-for-Delay" Settlements in the Pharmaceutical Industry: How Congress Can Stop Anticompetitive Conduct, Protect Consumers' Wallets, and Help Pay for Health Care Reform (June 23, 2009), *available at* http://www.ftc.gov/speeches/leibowitz/090623payfordelayspeech.pdf. (Noting at p.8 that "[t]hese numbers were based on pretty conservative assumptions. Perfectly reasonable alternative assumptions would lead you to $75 billion in savings for American consumers, which would work out to $25 billion for federal programs over the next decade.")

[ix] Scott Hemphill, testimony, Mar. 31, 2009, before the House Subcommittee on Commerce, Trade, and Consumer Protection, at 9, *at* http://energycommerce.house.gov/Press_111/20090331/testimony_hemphill.pdf.

[x] Community Catalyst organized the support of thirty-three national and local consumer and labor organizations for a ban on pay-for-delay settlements during national health reform. http://www.prescriptionaccess.org/2009lobbyletter20.pdf. For a description of organizations opposing these agreements in the Courts, see http://blog.prescriptionaccess.org/?p=807.

Bird-Dogging

Because we are in an election year, you may encounter opportunities in the next few weeks to attend public election events. During some of these rallies, town-hall meetings, or public debates, there may be opportunities for audience members to ask questions or meet the candidates. Bird-dogging is the process by which advocates and activists raise their hands or get up to microphones early and often in order to control discourse about a specific issue that they are interested in. In this case, we'd like you to bird-dog an event to ask those running for office what their stance is regarding Pay-for-Delay drug settlements.

This tactic is HIGHLY effective. In the 2008 presidential elections, bird-dogging by AMSA students and other activists was successful in securing verbal commitments (which specified a figure of $50 billion for PEFPAR reauthorization) from most of the leading presidential candidates. This bill was signed into law by President Obama in July 2009.

These notes derived partially from Bird-dog 101, which can be found at: www.tinyurl.com/birddog101

To Prepare

- Find a campaign event. They may be advertised in newspapers, on local news services, at local universities/schools, churches, etc...You may also choose to call the campaign to ask!
- Find out the event format. Do you need a ticket? How do you get one? When do doors open? Is there a Q&A period? Can you sign up to be a volunteer in order to get your friends to the best seats?
- Organize a group of friends to go with you. This will make it more fun for you and increase opportunities to get your issue heard!
- Write out your questions before hand.
- GO EARLY. Arrange a place where everyone can meet in order to brief folks about the issue, scope out the venues and to plan for the bird-dogging which will take place.

During the Event

- GO EARLY. Get good seats! Usually these are seats which are close to microphones or to front or to where candidates will likely walk in or out, or where s/he will go for handshakes.
- If the event is a lecture hall format: there will likely be ushers walking around with microphones after the main speech or debate. Grab seats in different areas of the auditorium and make sure that everyone in your group raises their hands (FIRST, FAST, and HIGH) in order to maximize chances of being called upon. Effective forum questions are longer (10-15 seconds) and usually follow this format: personal story or hook, fact, answer, and then question.
- If the event allows an opportunity for candidates to mingle with audience members, such as handshakes or photo opportunities, approach the candidates for hand shakes. Once you have their hand in yours, don't let go. Directly ask your short and concise question and don't let go of their hand until they give you an answer. Ask if they would support a bill which would ban Pay-for-Delay drug settlements (specify the bill number). These questions must be VERY short (usually yes or no type of questions) and clear enough to be understood despite numerous other questions which may come before or after yours. This is especially important because media will be present (local news crews, video cameras, journalists, etc...) to document on record what they say (Yes or No).
- If there are more than 1 person in your group, have cameras ready to document the hand-shake or question and response.

- Get quoted by sticking around to talk to press. If they ask you a question that is not related to Pay-for-Delay or generic drugs, redirect your answer so that you get your point across. Have a sound bite for whether the candidate says yes, no, or waffles.

After the Event

- Meet briefly with your group to discuss how things went.

- Please report back to us! Send an email at jluo4@uic.edu and ethan.guillen@essentialmedicine.org to let us know how it went. Please include the following information: event you attended, what candidates were present, date of the event, how many people were in your group, questions you were able to ask or answers which were given, and PRESS COVERAGE. Please also send us pictures if you took one!

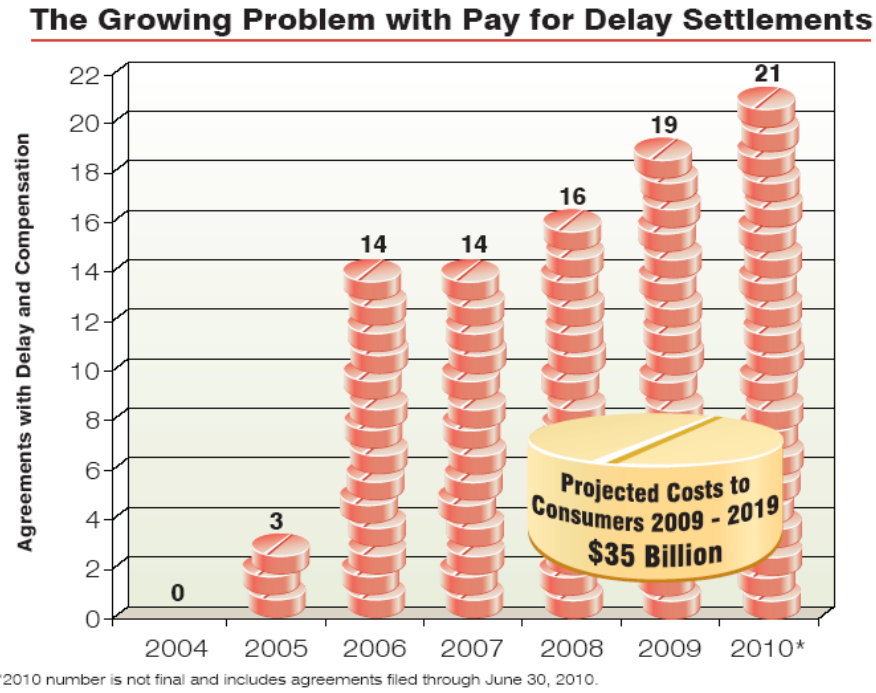
ACTION ALERT:
Help End Sweetheart Drug Deals

Access to affordable generic drugs improves care, while saving billions

Generic drugs have saved consumers and federal programs $734 billion over the last 10 years. Today, Americans fill 70 percent of their prescriptions with generics. As seniors and the underinsured struggle with out-of-pocket costs, low cost generic drugs can be a life-saver.

So what's the problem?

Sweetheart deals by the drug industry keep generics off the market! Brand-name drug makers pay millions to get generic drug companies to agree to keep a generic drug off the market. For example, ***Bayer paid $400 million to three different generic competitors to keep generics of the antibiotic Cipro off the market for six and a half years.***



Source: Federal Trade Commission (FTC)

These secret sweetheart deals ("Pay-for-Delay") are preventing generics from competing with $29 billion in annual brand-name drug spending! This makes it harder for doctors to prescribe drugs that consumers can afford!

What you can do:

The Senate Appropriation bill, S. 3677, includes new provisions that would help ban this kind of collusion between drug makers under consumer anti-trust law.

- ☐ Please visit (www.tinyurl.com/emailpay4delay) to send a message to your Senator and Congressperson in support of the ban on pay-for-delay settlements!
- ☐ Please urge your Congressperson to vote for this ban when it comes up in the House.
- ☐ Join the AMSA *Campaign to Increase Access to Affordable Medicines*

To join the campaign, or to find out more about how this collusion by the drug industry is harming patients while costing billions in unnecessary drug spending, contact **Jing** at: jluo4@uic.edu.

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Commonly Encountered Claims by Those Who Support Pay-for-Delay Settlements

(and How to Respond to Them!)

Understandably, those who benefit most from these collusive agreements (industry) are opposed to this legislation. Opponents include: Generic Pharmaceutical Association (GPhA), Pharmaceutical Research and Manufacturers of America (PhRMA), Intellectual Property Owners Association (IPO), as well as proxy economists, talking-heads, and patent lawyers funded by industry. Below are some of their common arguments.

Before engaging with those who support these pro-industry claims, I would encourage you to follow the advice of Pascal Diethelm, who has this to say about *denialists*: they will employ fake experts, selectively draw from isolated papers (or in this instance, case law), and will attack scientists as if they are anti-industry *crusaders*. It is important to recognize denialism where it exists and to avoid falling into direct debate with them.

1) **Patent settlements guarantee generic drugs reach the market before patents expire, providing billions of dollars in additional savings to consumers, taxpayers and the health care system.** The crux of this argument relies on the assumption that <u>some</u> Pay-for-Delay settlements result in the earlier entry of a generic drug than would otherwise be allowed if no settlement ever took place.
    a. Pharmaceutical companies have been required by law to file certain patent litigation settlements with the FTC since 2003.[7] Analysis by the FTC of these settlements showed that instead of resulting in EARLIER generic entry (an industry claim), settlements that included payment/compensation to the generic company resulted in DELAYED entry (by an average of nearly 17 months. That's 1.4 years!).
    b. Generic companies are most likely to challenge existing patents when they feel that they have the strongest case (i.e. when the patent being challenged is likely to be ruled by the court as being invalid or non-infringed). Pay-for-Delay settlements protect these weaker patents
    c. Another problem with the current court interpretations of Hatch-Waxman Act law is that a settlement with the first generic drug maker that files an application to get their generic version of the drug approved for sale by the FDA can block all other competitors from trying to bring the drug to the market. This prevents competition across the market, and hurts consumers.

2) **The legislation would undermine pharmaceutical patents by imposing a presumption that any settlement involving a payment to the generic applicant is to protect an undeserved patent.**
    a. The proposed ban on Pay-for-Delay presumes that settlements are anti-competitive, and a violation of federal anti-trust protections enforced by the FTC. However, drug

[7] Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the "MMA")

companies can overcome this presumption by showing that their settlement truly does not harm consumers or consumer markets.

3) **If a generic company cannot settle a lawsuit it has provoked by filing an ANDA (Abbreviated New Drug Application) and challenging the patents covering a drug product, it may choose not to bring a challenge in the first place.**

   a. While this is theoretically possible, it is not in the best interest of US consumers to protect the ability of generic companies to file frivolous patent challenges if the primary reason for filing such challenges was to win a reverse-payment settlement.

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