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Before the

UNITED STATES SENATE
SPECIAL COMMITTEE ON AGING

The Generic Drug Maze: Speeding Access to Affordable, Life Saving Drugs

July 20, 2006

Good Morning Chairman Smith, Ranking Member Kohl, and all the Members of the Senate Aging Committee.

I am Mark Merritt, President of the Pharmaceutical Care Management Association (PCMA). PCMA is the national association representing America's pharmacy benefit managers (PBMs), which administer prescription drug plans for more than 200 million Americans with health coverage provided through Fortune 500 employers, health insurers, labor unions, and Medicare.

I am pleased to be here today to discuss barriers to generic-drug entry into the marketplace. It is estimated that approximately $12 billion in brand-name drugs are anticipated to lose patent protection in 2006; another $11 billion in 2007; and $10 billion in 2008; increasing global sales of generic drugs from $29 billion in 2003 to $49 billion in 2007.[1] [2] Given the unprecedented levels of brands coming off patent, PCMA believes that this is a timely and important hearing and we applaud the Committee for its leadership.

PBMs' PROVEN TRACK RECORD

First, let me provide you some background on PBMs. PBMs have a long and distinguished record of administering drug benefits in the commercial marketplace – including designing and implementing cost-effective generic drug-utilization programs. As a result, PBMs have generated savings averaging 25 percent compared to unmanaged drug expenditures, although the savings PBMs achieve with generics are generally much deeper.

PBMs have a strong track record for delivering quality prescription-drug benefits with generous savings for consumers and purchasers. PBMs generate increased efficiencies by pooling the purchasing ability of millions of consumers to foster price competition between drug manufacturers and retail pharmacies where none previously existed. PBMs generate savings and improve quality by using cost containment, clinical, and utilization-management tools designed

[1] Drug Topics, Generics Supplement, April 2006

[2] "Use of Generic Therapeutic Substitution Can Save Billions in Drug Costs", Drug Benefit Trends, March 2006.

to balance consumers' and purchasers' needs for affordability, choice, and access. Such tools include:

- pharmacy and therapeutic (P&T) committee formulary development and review;
- pharmacy network management;
- negotiation and administration of product discounts, including manufacturer rebates;
- mail-service pharmacy;
- drug utilization review (DUR);
- generic substitution;
- clinical prior-authorization and step therapy;
- consumer and physician education;
- disease management; and
- prescription compliance programs.

Throughout the health care system, and now including the Medicare program, pharmacy benefit management tools are recognized as essential to improving outcomes and ensuring value-based purchasing. Prior to the advent of these tools, there was no system-wide approach that fully addressed the real dangers associated with misuse, overuse, or underuse of prescription drugs and escalating prescription drug costs.

PBMs' tools have delivered results. A recent study published in *Health Affairs* by CMS actuaries revealed that prescription drug spending in 2004 slowed to its lowest growth rate in the past 10 years, rising 8.2 percent. Since 1999 alone, the rate of growth in prescription drug spending has dropped by more than 50 percent. Overall, health spending grew in 2004 at a 7.9 percent clip, down from 8.2 percent in 2003.[3] The study's authors cited the rapid growth in the use of lower-priced generic drugs and mail-service pharmacies as two of the four key reasons.

[3]Smith, Cowan, Heffler, et al, CMS National Health Accounts Team, "National Health Spending in 2004: Recent Slow-Down Led By Prescription Drug Spending", *Health Affairs*, 25, no. 1 (2006: 186 – 196).

GENERICS REDUCE COSTS FOR CONSUMERS & PAYERS

It is estimated that every 1 percent increase in generic utilization results in 1-2 percent total cost savings. The brand and generic cost differential is on average between $60-80 per prescription.[4] For example, the average brand-name prescription in 2004 was $96.01, compared to the average generic prescription price of $28.74.

PCMA recently examined the top 100 drugs used by seniors to arrive at a conservative estimate of potential cost-savings to Medicare and the entire health care system. We found that at least 14 brand-name drugs commonly used by seniors to treat conditions such as high cholesterol, depression, heart disease, and hypertension are anticipated to go off patent or lose exclusivity during the next five years. Since generic drugs cost an average 30 to 80 percent less than brand-name drugs, the savings are huge.[5] PCMA calculated that from 2006 to 2010 the savings across the entire health system would be $49 billion as a result of these drugs going generic. Seniors and the Medicare Part D program could potentially save, at a minimum, more than $23 billion dollars over the next five years.[6]

	2006	2007	2008	2009	2010	2006-2010
Potential Savings from drugs going generic in 2006	$3,203,013,699	$5,832,000,000	$5,832,000,000	$5,832,000,000	$5,832,000,000	$26,531,013,699
Potential Savings from drugs going generic in 2007	$0	$1,453,946,301	$4,422,600,000	$4,422,600,000	$4,422,600,000	$14,721,746,301
Potential Savings from drugs going generic in 2008	$0	$0	$1,472,202,740	$2,106,000,000	$2,106,000,000	$5,684,202,740
Potential Savings from drugs going generic in 2009	$0	$0	$0	$301,808,219	$2,160,000,000	$2,461,808,219
Total Potential Savings	**$3,203,013,699**	**$7,285,946,301**	**$11,726,802,740**	**$12,662,408,219**	**$14,520,600,000**	**$49,398,770,959**

Source: PCMA analysis, April 2006

[4] Generic Pharmaceutical Industry Association, http://www.gphaonline.org. Accessed May, 2006

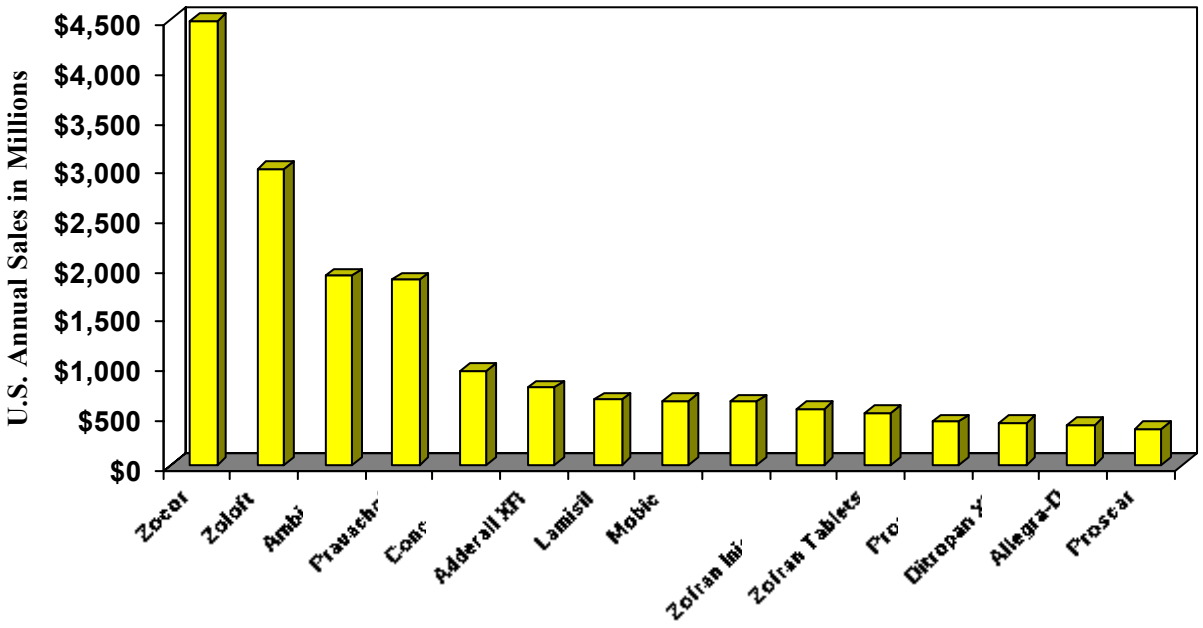
[5] Generic Pharmaceutical Industry Association, "About Generics," Accessed April 6, 2006, available at http://www.gphaonline.org/Content/NavigationMenu/AboutGenerics/Statistics/Statistics.htm

[6] Pharmaceutical Care Management Association Analysis, April, 2006

PBMs' ROLE IN PROMOTING THE USE OF GENERIC DRUGS

PBMs have played a critical role in encouraging the use of generic drugs as part of the comprehensive drug-benefit services provided to plan participants and our clients. One PBM estimated that it saved its clients $322 million in 2005 through its generic-related initiatives. In 2006, there is an almost unprecedented amount of branded drug spend that is expected to lose patent protection. In particular, patent expirations on Zocor and Pravachol will offer payers and patients their first significant opportunity to realize big savings in one of the largest drug classes, anti-cholesterol medications. PBMs work with clients to develop plans to maximize the uptake of these new generic entrants, as well as the other numerous drugs expected to go generic this year.

Brands with Expected Generic Launches in 2006-2007



PBM generic drug programs have greatly impacted generic substitution rates (GSR). For example, in 2005 one PCMA member company had an overall GSR of 93.5 percent, with their mail-service pharmacy achieving a high GSR faster than retail pharmacies. Within 1 month of a new generic drug becoming available, a mail-service pharmacy can have success in substituting the new generic for the brand more than 90 percent of the time. In contrast, it may take a retail pharmacy three or more months to achieve the same substitution rate.

PBM programs increase generic utilization through consumer and physician education programs, plan design, e-prescribing, and the use of mail-service pharmacies.

- **Plan design:** PBMs implement a variety drug-plan design options that encourage the use of generic drugs. These options include reduced copayments for generic drugs; step therapy programs that encourage doctors to prescribe the brand medication only after the patient has tried the generic first; and, in some cases, physician authorization for the brand product when a generic product is available.

- **Education/Incentives/Interventions/Communications:** Through proactive, concurrent and retrospective programs, PBMs empower and educate physicians, pharmacists, and patients about the safety and effectiveness of generic drugs.

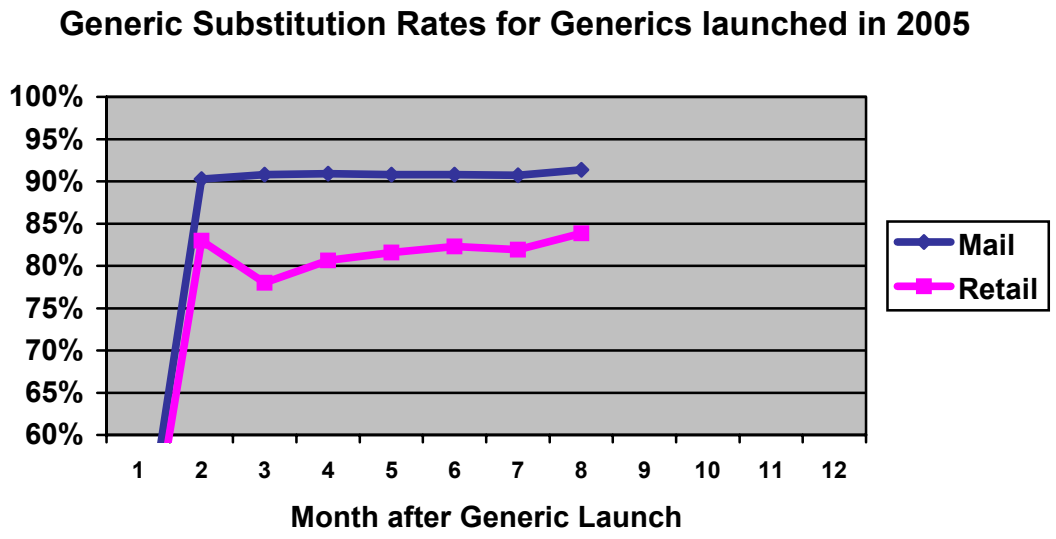
    - **Physicians:** Physician outreach includes sampling programs, education through retrospective DUR (drug utilization review) letters, and physician profiling and report cards. The final decision to dispense a brand or generic drug rests with the prescribing physician.

    - **Patients:** Education tools include general and direct mailings explaining the value and affordability of generic drugs. Patient-specific mailings are sent when a patient is identified as using a brand when a generic equivalent is available.

- **Pharmacists:** In addition, PBMs educate pharmacists through on-line communications at the point-of-sale that alert the pharmacist to a generic drug's availability. PBMs also provide incentives such as higher dispensing fees to encourage the dispensing of generic drugs and provide extensive analytic and reporting tools to aid pharmacies in improving generic substitution rates.

- **E-Prescribing:** One of the most vital programs to assist in the dispensing of generic drugs by physicians is electronic prescribing (e-prescribing). E-prescribing gives physicians the ability to view the range of prescription options at the point-of-prescribing, along with the patient's medication history and specific drug-formulary information. In addition, as it often easier to prescribe, pronounce and spell the brand name drug, e-prescribing is even more valuable as a tool to encourage generic substitution at the point-of-prescribing. E-prescribing allows for a better dialogue between the physician and the patient and avoids calls to the physician's office to ask for a generic-drug substitution after the prescription has already been written.

- **Mail-Service Pharmacy:** An FTC study last year noted that PBM mail-service pharmacies are efficient in encouraging the use of generics. [7] As I mentioned previously, PBMs can reach a higher GSR much faster through mail service pharmacies than at the retail pharmacy counter.



[7] "Pharmacy Benefit Managers: Ownership of Mail Order Pharmacies", Federal Trade Commission, August 2005.

OPPORTUNITIES FOR CONGRESS AND THE ADMINISTRATION

While I'm not a patent lawyer, I do believe that PBMs are in a good position to speak to the economic impact that delayed entry for generics has on payers. Generic drugs now account for about 12 percent of the nation's $250 billion annual in drug spend and more than 53 percent of prescriptions filled. IMS Health, a company that tracks the industry, predicts that the market share of generics will exceed 65 percent within four years as several blockbuster drugs go off patent.

Because current generic substitution rates are generally over 90 percent, the greatest opportunity today to increase the savings realized from generic drugs lies in increasing the availability of generic drugs generally.

There are many factors that create barriers to the availability of generic drug alternatives. Some of these barriers can be addressed by Congress and the Administration. PCMA urges action to eliminate unnecessary barriers that keep generic alternatives from entering the marketplace. Following are four areas where PCMA believes Congress and the Administration should take action to significantly increase generic drug utilization:

1. **Support S. 2300 to close legal loopholes;**
2. **Create a legal pathway for generic biologics;**
3. **Increase funding for the Office of Generic Drugs; and**
4. **Create a national, uniform standard for e-prescribing.**

1. CLOSING LOOPHOLES

With the passage of the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Act, Congress established an abbreviated new drug application (ANDA) process for faster generic-drug entry onto the market. Over time, brand-name manufacturers have found loopholes in the Act that allow them to extend their patents beyond the initial period, thereby frustrating the purpose Hatch-Waxman and delaying the introduction of generic drugs to market. MMA took some corrective actions by eliminating

abuses of the 30-month stay and delaying the start date for the 180-day exclusivity period for generic manufacturers. However, there is still work to be done in order to ensure that the Hatch-Waxman Act removes *all* barriers that exist to increased competition and generic drug availability.

Specifically, PCMA would like to commend the goals of S.2300, The Lower PRICED Drugs Act, designed to close some of those loopholes. S.2300 was introduced by Senator Stabenow and is cosponsored by Senators Lott and the Ranking Member of this Committee, Senator Kohl. The bill has support from a wide range of interest groups including PCMA, the National Association of Chain Drug Stores, General Motors Corporation, Caterpillar, Inc., DaimlerChrysler, Ford Motor Company, AARP, Families USA, and the AFL-CIO, among others. We believe that it provides an excellent starting point for discussion of these important issues.

Specifically, S. 2300 seeks to do three very important things:

1. Reform the Citizen Petition process;
2. Reduce the delay in generic entry when patents are challenged in court; and,
3. Provide an avenue for additional generic antibiotics through its reforms.

Citizen Petitions. The Citizen Petition process was intended to allow citizens to raise questions for FDA's consideration relating to drug products. While PCMA believes that the process of identifying health and safety concerns is an extremely important one, we believe the process must be reformed. One investment firm recently stated, "…One of the easiest devices a branded company uses to delay generic competition is the Citizen Petition (CP). Anyone can file a CP, and this act alone typically triggers the suspension of any final FDA approval of a generic drug."

In fact, the OIG issued a report identifying FDA problems associated with CPs and the FDA subsequently issued draft regulations to address the concerns raised in the OIG report. The FDA later withdrew its draft regulations.

There is some evidence that the brand drug industry has been using the CP process to delay entry of generic drugs to the marketplace. The Lott-Stabenow bill would seek to curb this activity by:

- Requiring the generic approval process to move forward while a petition is considered;
- Requiring that final action on a petition be taken within 6 months of the petition being received;
- Requiring that petitions be signed and include a verification that the petitioner has taken reasonable steps to ensure all relevant information is included in the petition; and
- Ensuring that generic applicants don't lose their 180-day exclusivity solely because a citizen petition has been filed.

Patent Challenge Clarification. Before a generic drug can come to market, the generic applicant must get FDA approval and state whether it will challenge any of the relevant patents held by the brand manufacturer. This challenge often spurs a lawsuit by the brand that triggers a 30-month delay before the FDA can approve the generic drug. Although the law states that the courts may shorten the 30-month "stay" period, the stay is very rarely shortened, even in cases of egregious brand company delay tactics. While the MMA closed some loopholes regarding the 30-month stay, some brand-name manufacturers continue to deliberately delay the generic approval process. The delay tactics can and do prevent generic availability. S. 2300 would clarify that the courts should consider whether brand manufacturers are unnecessarily delaying the generic approval process.

Generic Antibiotics. Certain antibiotics licensed prior to November 12, 1997 are not listed in the FDA's official compilation of drug patents commonly called the "Orange Book." Because they are not listed, the generic alternatives are precluded from coming to market even though they may be safe and effective and, as a result, Americans are denied the generic versions of this essential category of drugs. S. 2300 would allow the generic versions for which patents are not listed in the Orange Book to enter the market.

2. GENERIC BIOLOGICS

Biologics are drugs to treat complex, chronic conditions and are extremely costly and remain costly over a long period of time because there is currently no competition in the market. The huge growth in biologics, or specialty drugs, is expected to reach $90 billion by 2009. This explosive growth is challenging because there is currently no legal pathway for generic biologic competition. Last year alone the cost of biologics soared 17.5 percent compared with traditional drugs which increased 10 percent. [8]

Challenges in Creating a Regulatory Pathway for Biogenerics

Biologics differ from traditional drugs in that they are typically large molecule products derived from living organisms rather than chemicals which are used to create tradition drugs. Their development and manufacturing are typically very complicated which is why most biologics have both content and process patents. The traditional drug approval process is typically regulated by the Food, Drug and Cosmetic Act (FDCA). Most biologics, on the other hand, are regulated under the authority of the Public Health Service Act (PHSA).[9] FDA regulates drugs and biologics under these different authorities. There is disagreement about how much authority FDA has to approve biogenerics. Legislation is needed to establish a clear pathway for biogenerics to enter the market and increase competition.

While some argue that the science of creating biogenerics is not fully developed, progress is being made daily to better understand how to analyze and evaluate the clinical evidence that will prove bioequivalence. Few dispute that there is a need for Congress to act to create a clear legal pathway for the widespread development of biogenerics.

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[8] Express Scripts, "Drug Trend Report 2005", June 2006.

[9] From FDA: The FD&C Act defines drugs by their intended use, as "(A) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease and (B) articles (other than food) intended to affect the structure or any function of the body of man or other animals" (FD&C Act, sec. 201(g)(1)). A biological product is defined, in relevant part, under the PHS Act, as "a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, or blood component or derivative, allergenic product, or analogous product . . . applicable to the prevention, treatment or cure of a disease or condition of human beings." (PHS Act, sec 351(i)).

Action in Europe

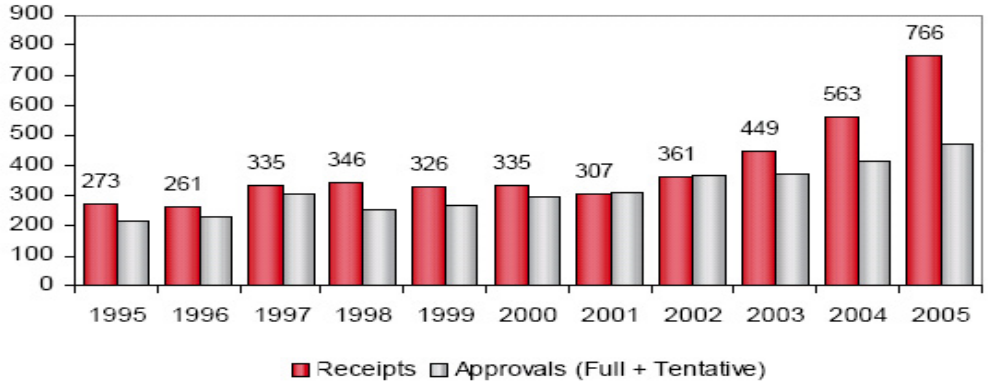
The European Union has approved legislation which creates a regulatory pathway for the approval of biogenerics. Europe's FDA-equivalent regulatory body has adopted regulatory guidance for considering biogenerics on a product by product basis. To date, they have approved generic versions of Omnitrope and Valtropin under this guidance. Further action is anticipated on products like Epogen in the near future.

PCMA believes that Congress should not wait until the cost of biologic drugs hits critical mass and the health care system is in crisis. PBMs must be allowed to exhaust every avenue to promote competition and define value for products through competition in the market. PCMA encourages Congressional action to establish a legal pathway for competition.

3. OFFICE OF GENERIC DRUGS (OGD) AT THE FDA

Published reports have highlighted that the generic drug backlog at the FDA is at an all-time high of more than 800 applications. While the OGD approved 361 generic drug applications in 2005, it actually received 766 generic applications in 2005. As a result, experts say, fewer generic drugs will be available to consumers in the years ahead than the industry is ready and able to provide. The FDA backlog is expected to balloon in the next few years given the volume of generics coming to market.[10]

Pace of Approvals Not Meeting Pace of Submissions



Source: FDA, Banc of America Securities

[10] Kaufman, Marc. "Generic Drugs Hit Backlog At FDA." *Washington Post*, February 4, 2006

With a large backlog of generic drug applications pending and more coming into the FDA every month, it is vital that the necessary resources are provided to the OGD now to insure review of these applications occurs within the statutory limit of 6 months. Currently, FDA estimates the average review time is 15 months and projected to increase to 17.5 months in the year. It takes OGD up to two years to fully train qualified examiners. PCMA supports increased funding this year to resolve the backlog that will only worsen over the coming years and applauds the work of Senator Kohl in helping to secure such funding. In addition, it is important that the FDA not be allowed to divert those funds to other programs or offices.

4. E-PRESCRIBING

PBMs promote electronic prescribing (e-prescribing) which has had a positive impact on patient care and the use of generic-drug alternatives. Physicians are often not fully aware of brand-to-generic substitution opportunities. In addition, it's often easier to prescribe, pronounce and spell a brand name drug name (e.g., Dyazide) than a generic one (hydrochlorothiazide/triamterene). Therefore, e-prescribing technology is particularly important as it allows physicians to view the range of generic alternatives available, along with the patient's medication history, and the patient's specific drug formulary information in order to make a more personalized, informed decision with the patient right there.

In one demonstration program started in February 2005 and using e-prescribing technology, three large employers teamed up to improve quality and determine the effects on prescription drug costs. They found that e-prescribing technology increased the generic use rate by 7.3 percent resulting in $3.1 million in savings for one year.[11] According to information on one of the employer's website, they found significant benefits for patients, physicians, pharmacists, and employers. For patients, there was greater safety, cost savings, convenience, and time saved.

[11] "HAP, Henry Ford Health System e-Prescribing Technology Hits 500,000 'Scripts", Henry Ford Health Systems, http://www.henryfordhealth.org/body.cfm?id=46335&action=detail&ref=560. Accessed July 2006.

The benefits for physicians also included safety and time savings, but found a more efficient workflow process, as well. For pharmacists, there was less wait time and the elimination of illegible hand-written prescriptions that can result in mistakes. Finally, the American College of Physicians stated that with 3 billion in prescriptions each year, universal adoption of e-prescribing could save $27 billion annually through the reduction in medical errors, hospitalizations, and formulary compliance.

Regrettably, the regulations implementing the new MMA only established a uniform e-prescribing standard only under Medicare. The myriad of state e-prescribing laws and now the 51st Medicare standard for e-prescribing has done little to encourage physicians to adopt the new technology. PCMA believes that the adoption of a national, uniform standard for e-prescribing laws would greatly encourage compliance by physicians and others and would lead to greater generic drug utilization. PCMA recommends regulatory or statutory clarity to create a national, uniform standard for e-prescribing across both government-funded and commercial books of business.

CONCLUSION

PCMA is pleased to have had the opportunity to testify here today and we look forward to working with the Committee as it considers these issues further. I would be happy to answer any questions Members may have.