Pfizer Inc Written Testimony on Electronic Prescribing Standards to the National Committee on Vital and Health Statistics Subcommittee on Standards and Security

July 29th, 2004

This written testimony contains Pfizer's oral testimony on electronic prescribing standards under the Medicare Modernization Act supplemented by additional comments on some of the more technical aspects of e-prescribing. These additional comments, interspersed throughout this document, are indented and italicized to distinguish them from the oral testimony.

Introduction

Good morning. My name is Peter Brandt. I am a senior vice president of Pfizer Global Pharmaceuticals and Chairman of the Board of Amicore – a joint venture company created by Pfizer, IBM and Microsoft that develops and provides integrated clinical and practice management solutions to small- to medium-sized physician groups.

Thank you for the opportunity to testify before the Subcommittee and for including all stakeholders in these important discussions. While I do not have a technical background per se, I have provided leadership for many of Pfizer's technology-based initiatives and will be providing testimony based largely upon those experiences.

Pfizer is the world's largest private research organization and pharmaceutical manufacturer. Our mission is to advance the quality and safety of healthcare through the research and development of innovative new medicines and health management services.

Importance of Policy Standards for eRx under MMA in Shaping the National Health Information Infrastructure

To this end, we are strong supporters of electronic medicine and enhanced connectivity through the creation of a National Healthcare Information Infrastructure. An interoperable eHealth infrastructure will greatly assist us in the search for new cures. It also will improve patient care by making clinical information more readily accessible to providers.

Equally important, it will also allow us to assess and more accurately address issues of disparities in access to care and patient compliance with prescribed therapy, and will enhance the overall benefit of the medicines we offer.

The Medicare Modernization Act charges this Subcommittee with making recommendations to the Secretary of Health and Human Services on standards for electronic prescribing. The impact of your work will reach far beyond this discrete issue, however. As Senator Bill Frist said in last week's NHII Conference here in Washington, DC, "As the MMA goes, so goes the rest of the nation."

In other words, as the e-prescribing standards for Medicare are put into place, all future efforts will have to be compatible with both the policies and technologies that result from your work. You are, in fact, laying the foundation for America's healthcare IT infrastructure. Many who have already testified – including physicians, technology vendors and standards organizations – have echoed this sentiment.

E-prescribing systems that are well implemented promise many benefits; if however, e-prescribing is implemented inappropriately, it could have profound adverse consequences. Given that we are dealing with the health and lives of patients, we should seek the foresight to head off these potential deleterious impacts before they occur.

To this end, I think it is useful in framing this important discussion to distinguish between the *technology* standards that will make an electronic prescribing program possible and the *policy* standards that will establish the ground rules for its use. *Both* sets of standards are essential components of a functional and sustainable e-prescribing infrastructure.

The Subcommittee has already heard a great deal of testimony on technical standards, but significantly less on the equally critical policy standards. The written testimony we have already submitted focuses mainly on technical issues. In my remarks today, I want to give attention to policy standards for electronic prescribing under Medicare.

We understand that any conversation on policy standards can be clouded by the specific, short-term needs and interests of the moment. A sustainable policy platform, however, *must* rise above these short-term concerns if it is to stand the test of time.

This is one of the reasons we funded the RAND e-prescribing quality standards study presented to this Subcommittee by Dr. Bell in May – to better inform the discussion on policy standards so that they would focus on clinical outcomes and patient safety as emphasized in the study's findings.

Pfizer's Core Principles on eHealth

The knowledge gleaned from the RAND study and other research has helped Pfizer develop a series of core principles on eHealth. These principles are consistent with most of the testimony you have heard.

We use these core principles as something of a litmus test to evaluate any proposal on the subject – including our own business strategies – to make sure they align with our mission of improving the quality and efficiency of healthcare for patients in the U.S. and around the world.

At the heart of these core principles are three basic tenets:

- Put the patient first;
- Support the clinical judgment of professionals without controlling them; and
- Ensure the integrity of the information used in clinical decision-making.

Protecting the Physician-Patient Relationship in Electronic Prescribing

"Putting the patient first" in electronic prescribing means that standards should be created to ensure patient access to appropriate care under the guidance of a skilled professional who is free to interpret and apply clinical evidence to an individual patient's situation.

Appropriately designed, e-prescribing tools can strengthen the vital relationship between a patient and doctor by reducing the time required for administrative work and information management; properly integrated, the information available to them will be far richer than it is today.

Alternatively, information technology can compromise – even irreparably harm – the quality of the physician-patient relationship. The greatest threat is that third parties may use e-prescribing to infiltrate and inappropriately influence the clinical decision-making process at the critical point-of-care. These intrusions, driven by financial interests, represent inappropriate influence and rarely have the patient's best interests at heart.

Indeed, the drafters of the Medicare law recognized this risk. I quote: "The conferees intend for electronic prescribing to serve as a vehicle to reduce medical errors and improve efficiencies in the health care system, *but not for it to be used as a marketing platform or other mechanism to unduly influence the clinical decisions of physicians.*"[1] This language applies to pharmaceutical manufacturers, pharmacy benefit managers, retail pharmacies, technology companies, and payers. We believe this intent should be honored by this Committee and by CMS as they develop standards for this program.

Instead, we believe that these tools must be designed with our *second* core principle in mind, that is, to provide decision *support* rather than decision *control*. What we mean is that the movement toward electronic prescribing should be about *supporting* the patient-physician relationship and shared decision-making, rather than exercising control over their relationship and decisions.

In May, the Subcommittee heard testimony that suggested there was no longer any reason to be concerned about external stakeholders interfering with the decisions of prescribers – that this was a relic of the excesses of the dot-com era. I can assure you that this "relic" is alive and kicking. Within the last year, companies offering financial incentives to help us influence the physician prescriber have approached both Pfizer and Amicore.

In other words: these companies were proposing an electronic method to help us step into the middle of the patient-physician prescribing moment. Our refusal to follow through on their offer stems from our fundamental belief that no third-party entity should unduly influence decision-making at the point-of-prescribing. In fact, no third party could *possibly* understand or account for all the factors that inform the decision for that particular patient.

[1] H.R. Conf. Rep. No 108-391, at 456 (2003).

For example, a doctor may be trying to prescribe an extended release form of a drug for a patient with a cognitive disorder to simplify treatment and improve compliance. A message could pop up:

The four-times-a-day dosing is preferred. Do you want to change?

No.

Are you sure?

Yes.

The QID dose form is 15% cheaper…

…thereby, frustrating the physician by adding unnecessary steps to complete the prescription.

Or it could be as subtle as changing the order of the medication list so that the drug preferred by the third party remains at the top of the list, or on the first screen – not because it has a clinical advantages over other drugs in the class or even because it costs less, but rather because its maker provides the biggest manufacturer rebate. We have seen a number of instances of this type of profit-based interface bias and believe it has no place in medicine.

At Pfizer we believe strongly in informing consumers and physicians about the benefits of our medications. We actively provide medical education about our product consistent their FDA-approved uses. But we do not believe that Pfizer or anyone else should be influencing or coercing the doctor as the pen hits the prescription pad – or as the stylus clicks the screen. That simply does not put the patient first.

We therefore ask the committee to recommend standards for ensuring that a zone of autonomy surrounds the physician-patient relationship and protects that relationship from commercial messaging, defined as any influence from any third party – be it a payer, PBM, pharmacy, technology company or manufacturer – and that this zone of autonomy be protected by carefully crafted policy standards and related technical standards to ensure that this protection is not eroded over time.

In making this request, it is important that I differentiate between the passive, neutral presentation of the formulary and other types of commercial messaging. Accurate formulary information helps inform the prescribing decision. The formulary should not, however, be used as a tool for decision control, but rather as decision support.

Information Integrity in Electronic Prescribing

Turning to another equally important policy standard, I will now discuss the importance of ensuring the integrity of clinical information used in decision-making. Electronic prescribing can connect physicians to contextually sensitive information about drug therapies – and about their patients – to allow them to make an informed clinical decision.

We believe that third-party information relevant to the decision-making process should be made available at the point of care. However, there currently is no mechanism to ensure that the information presented to aid decision-making is factually correct, reasonably applicable, properly sourced, or subject to consistent and rigorous standards of accountability or balance.

Indeed, the Congress recognized the need for accurate, balanced formulary information when the conferees expressed their intention that physicians have ready access to, and I quote, "neutral and unbiased information presented on the full range of covered outpatient drugs available."[2]

An appropriately designed e-prescribing tool can present the source of information, but it will take a policy standard – again hopefully reflected in some way within the technical standard – to enforce the use of this capability.

Hence, consistent with our third core principle of maintaining information integrity, *we ask that a policy standard be created to assure that the information presented within the e-prescribing environment is properly sourced and that the parties who put forth information are subject to the same rigorous standards of accountability and balance as required by the FDA for pharmaceutical manufacturers.*

> *Pfizer's position with regard to information integrity within e-prescribing is analogous to the position that the FDA took in 1998 when it proposed to regulate PBMs. In the 1990s, several pharmaceutical companies acquired or entered into agreements with healthcare organizations and PBMs in which the PBMs would promote their products, including the dissemination of promotional labeling and advertising. The agreements between the PBMs and pharmaceutical sponsors often provided product-specific incentives for the PBM to influence prescribing decisions.*
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> *In some cases, patients on chronic drug therapy were switched from one product to another as a result of these incentives. In an effort to affect the market share of specific products, a PBM could enforce restrictions on prescribing decisions or disseminate promotional materials designed to influence prescribing decisions toward particular products and away from their competitors. In fact, the U.S. General Accounting Office found that the objectives of the mergers between pharmaceutical sponsors and PBMs was the belief that the PBMs' market power would help maintain the manufacturers' profits at a time when their drugs faced increased competition.*
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> *While the FDA had the ability to regulate the promotional activity of pharmaceutical companies, it didn't normally regulate materials disseminated by individuals or entities not affiliated with a pharmaceutical company, such as a healthcare organization or PBM. The FDA felt that the pharmaceutical companies shouldn't be able to avoid regulation by changing the form through which their communications are accomplished. Thus, the FDA wanted to regulate the promotional activities for many of the same reasons that Pfizer is advocating for e-prescribing standards. The FDA was concerned about promotional activities that may create a public health risk.*

[2] H.R. Conf. Rep. No 108-391, at 455 (2003).

The FDA was likewise concerned that promotional materials disseminated to healthcare providers and patients would result in inappropriate medical decisions if the information were false, misleading, or promoted an unapproved use. Thus, the FDA, like Pfizer, was concerned that, without proper regulation, the quality of information presented to physicians would suffer.

The FDA, like Pfizer, also wanted to ensure the sanctity of the patient/physician relationship – that the doctor and patient together were making prescribing decisions and not a third-party with a financial stake in the decision. Finally, the FDA, similar to Pfizer, wanted to maintain a level playing field for all medical product sponsors.

Capturing Differentiating Features of Medicines in Electronic Prescribing

I would like to make another important point about "putting the patient first" and how the rights and needs of the *individual* patient seeking care should drive the design of standards for eHealth.

Within the electronic prescribing environment, there are tremendous opportunities to provide individualized medicine that delivers a patient's medical history and medication history to the point of care. But that same tool can also be used to create a barrier to appropriate care.

How so? If the e-prescribing tool does not account for a patient's *individual* clinical needs, life circumstances, and personal values – if it simply enforces the application of a population mean or generalities about populations – it removes from the physician's clinical decisions the very factors that allow patients to receive care appropriate to their unique needs.

It reduces the physician to dispensing one-size-fits-all solutions.

Let's take the area of *differentiating features* as an example – where something that seems relatively straightforward may in actuality create significant problems if it is not designed to account for the uniqueness of individual patients. An e-prescribing tool needs to contain more information about each medication than its chemical composition, dose, and the forms in which it is available.

Physicians also need to be able to know things like the availability of compliance packaging, flavorings, the absence of gluten or animal products, and so forth. Our experience in providing information to patients and clinicians about our products and the science behind them tells us that these issues are anything but minor. In fact, no single feature is insignificant when you're talking about individuals.

Why? Well, consider the simple matter of gluten content. As many as one in three hundred people cannot tolerate having any gluten in their diets. A physician who prescribes a medicine containing gluten for some other condition could harm his patient.

A similar concern can arise around medicines containing ingredients derived from animals or humans because of a patient's personal or religious convictions. When such an issue is discovered *after* the patient gets home with her prescription, it can result in the most expensive kind of healthcare there is: the treatment that is paid for but not used.

Importantly, adding differentiating features to the e-prescribing process will allow prescribers and patients to clearly articulate their needs at the point of care and find appropriate products that will fill these needs. Currently, there are no standards in place for cataloguing and communicating these differentiating features.

As we explain in more detail in our written testimony, one solution may be to adapt the FDA's Structured Product Labeling initiative for this purpose as the source of the content for these features and then modifying relevant portions of NCPDP SCRIPT and HL7 to transmit this information. *We therefore ask the Subcommittee to put patients first by recommending the development of these standards for accommodating the differentiating features of medicines.*

> *The capture of differentiating features is particularly important within the context of e-prescribing because of the changes in e-prescribing workflow relative to the paper-based process. With a paper prescription, the patient typically presents the prescription to the pharmacy and can articulate special needs to the pharmacist – such as the need for a gluten-free prescription – before their prescription is filled and dispensed. With electronic prescribing, the prescription is sent directly to the pharmacy and is often filled before the patient arrives. The patient doesn't have an opportunity to provide this additional information before the solution is mixed or the pills counted and put in a bottle for dispensing.*
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> *The FDA's Structured Product Label (SPL) will capture many of the unique features of a prescription medicine in a structured format. Some of these features – such as the compliance packaging that would be found in a tapering dose package for methylprednisolone – are already accounted for within the current SPL format. Others will still need to be accommodated.*
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> *Based upon our preliminary investigation of this issue, we would recommend that the FDA develop a controlled vocabulary for differentiating features and incorporate this vocabulary into the structure of the SPL. This vocabulary would be limited to those features which manufacturers and the FDA together agree are most relevant to the prescribing decision making process from a clinical and individual patient perspective. This vocabulary would include negation indicators (no animal products, no gluten) as well as positive attributes (banana flavoring).*
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> *The vocabulary would be controlled by the FDA to ensure that only relevant differentiators are included. When a manufacturer develops a novel differentiating feature, the manufacturer would submit a request for an expansion of this controlled vocabulary to include this feature. The FDA would develop a process for accepting or rejecting these requests.*

Once this controlled vocabulary is developed and incorporated into the SPL, accommodations for its transmission via NCPDP SCRIPT and HL7 would need to be developed. Currently, there are no mechanisms for sending this information in a structured fashion in either standard, though work has already begun to include this in HL7's Medication Model in version 3.0. For either standard, however, the information would be included in an unstructured portion of an e-prescribing message until such time as the standards are modified to accommodate this message.

In its final form, adding differentiating features to the e-prescribing process will allow prescribers and patients to clearly articulate their needs at the point of care and find prescribable products that will fill these needs. For example, the e-prescribing tool could be structured in a way to show the basic prescribable medicine (RxNorm-level data of ingredient, dose form and strength) on the screen with an icon ⊕ indicating that this medicine is packaged with various differentiating features that may be of interest. If the top-level product is sufficient, the prescriber can ignore these features and prescribe it at the RxNorm level.

But if the patient needs a gluten-free product, the prescriber could click on the ⊕ symbol and see if this feature is listed. If there is a product on the market that fulfills has this feature, the NDC number(s) associated with it would be linked to that differentiating feature code. The prescriber could then check a box or boxes for this and any other differentiating features required by the patient. Along with the RxNorm code, the differentiating feature codes would be electronically delivered to the pharmacy.

As more sophisticated e-prescribing tools are developed, many of these issues could be handled in the background without the physician's direct intervention.

To accelerate the development of the necessary standards for managing differentiating features of medicines, we ask that the Subcommittee recommend the inclusion of a controlled vocabulary for differentiating features into the SPL standard and that the NCPDP Script and HL7 medication standards be modified to enable transmission of electronic prescriptions that include this information.

Prior Authorization in Electronic Prescribing

The crafters of the MMA legislation took care to insist that the electronic prescribing program pose no undue burden on prescribers. But the current transaction standards do little to address some of the areas where physicians feel the greatest administrative burden.

One such area is Prior Authorization. The very automation and efficiency principles driving the adoption of e-prescribing are not being applied with equal vigor to the Prior Authorization process.

As a result, the PA process becomes more a means to control clinician behavior rather than an opportunity to optimize patient care – as physicians must leave the electronic prescribing process and resort to a paper- or phone-based process specifically designed to be an inconvenience.

Applying the core principles of "put the patient first" and "support but don't control clinical judgment" to this issue tells us that the best way to manage Prior Authorization is to make it a seamless part of the prescribing process.

As an example, H2 blockers can be prescribed to treat gastric reflux in children. While the tablet form of many of these drugs is available over the counter, the syrup solutions are not. As a result, pediatricians are forced to go through the onerous process of prior authorization (which usually involves repeated calls) simply to prescribe a formulation of a prescription that is not available over the counter for their particular patient population. How does this burden promote safety and efficiency?

The formulary should be structured and standardized in such a way that e-prescribing and EHR vendors can present information consistently and without bias; use intelligent tools to notify the clinician when the Prior Authorization requirements have been met; send the authorization request to the payer; and have the Prior Authorization code accompany the electronic prescription on its way to the pharmacy.

This is *precisely* the type of efficiency gain that the electronic prescribing program was intended to capture. Efficiency, not inconvenience, should drive the development of electronic prescribing. *We ask that the Subcommittee recommend the development of technical and policy standards in support of a structured formulary and automated Prior Authorization process.*

> *The lack of standards for incorporating Prior Authorization into the electronic prescribing process and the lack of standards for the structure of the formulary itself are both reflective of the need for a greater breadth of stakeholder involvement in the standards development process. Prescribers and patients are poorly represented as they do not have direct involvement in the electronic transactions made within e-prescribing. In some cases, it is important to provide some external impetus to drive the creation of these standards as there is a disincentive among payers in particular to ease this burden for prescribers and patients.*
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> *An analogy can be made to the situation recently experienced in the cellular phone industry. Until the cellular providers were required to do so, customers could not transfer their telephone numbers to another carrier, providing a barrier to competition. Likewise, there is little incentive for those requiring Prior Authorization to do anything that will make it easier to obtain prior authorization.*
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> *Pfizer asks that the Subcommittee recommend that standards be made to structure the formulary benefit so that it can be represented in the e-prescribing tool consistently across formularies without bias or confusion. For Prior Authorization standardization, Pfizer believes that the NCPDP SCRIPT is the most suitable candidate for expansion to accommodate this process as it is already being used to accommodate a number of similar transactions. Calling upon NCPDP to create these standards will ensure their development in a timely fashion.*

Closing

As I said at the onset of this testimony, we are pleased at the opportunity to present our views to the Subcommittee. We believe that the goals of electronic prescribing are well aligned with Pfizer's mission to advance human health through the research and development of medicines that allow people to add years to life and life to years.

But we also believe that in order for the full promise of electronic prescribing to be realized, it must be implemented in a manner that stays true to the three core principles I discussed this morning: Put the patient first; Provide decision support, not decision control; Ensure information integrity and balance.

We sincerely appreciate the hard work that has been invested in this effort, and we recognize the magnitude of its scope. Pfizer remains committed to the pursuit of health improvement through the application of innovative solutions in both medicine and technology and will work in partnership with you and all stakeholders toward this end.

Thank you.

Additional Issues for Consideration

Therapeutic Classification in Electronic Prescribing

Electronic prescribing can put the patient first when it embodies a sound therapeutic classification schema – that is, when its manner of identifying diseases or disorders and the medicines related to their treatment, are based on good science and careful clinical reasoning. This is why Pfizer supports the creation of a standardized classification schema by the US Pharmacopeia (USP).

If Prescription Drug Programs (PDPs) choose to restrict their formularies by reducing the number of classes they recognize, at a minimum, these variations should be mapped to the standard schema so that doctors can understand how the PDP's schema differs from the standard. We ask this Subcommittee to recommend that that the e-prescribing standards promulgated by HHS adhere to such a schema.

The MMA requests USP to draft a standard classification schema, which "may" be adopted by the PDPs in formulating their own schemas for benefit design. In consultation with many different stakeholders within NCPDP, Pfizer is concerned that employing multiple schemas within the Medicare program will lead to significant confusion among patients and clinicians.

While the structure of the benefit design is not specific to electronic prescribing and will impact paper-based prescribing as well as e-prescribing, some of the manifestations of variable schemas will be most notable within the e-prescribing environment. One could envision the prescriber seeing a clinically relevant medication covered with one patient and then finding that not only is the drug not covered in the next, but nothing in that therapeutic class is covered. Only after considerable effort would the prescriber come to understand that the PDP changed the classification itself.

In prior hearings, some of the drug compendia companies have indicated that they remain uncertain as to how they will represent these alternate schemas within their drug databases. We ask that this issue be investigated thoroughly as HHS makes policy decisions regarding the presentation of therapeutic classification within the context of electronic prescribing and make policy standards that lead to the greatest clarity and benefit for patients.

Access to Data for Research

In a related issue, Pfizer believes that the data generated through the use of electronic prescribing can go a long way toward discovering new applications for existing medicines as well as providing early indications of potential adverse events related to their use. The discovery of these relationships is dependent upon manufacturers maintaining access to the data generated through electronic prescribing. We ask that policy standards support the conduct of primary research through the use of such data so that pharmaceutical manufacturers like Pfizer have full access to appropriately de-identified data so that we can bring these new discoveries to bear on current and future innovations.

Unique Patient Identifiers

Finally, we would like to raise the concern that so many others have already raised in these hearings regarding identifiers: without appropriate unique patient identifiers that are assigned to a person and not to a relationship with a payer or clinician, we will all be severely limited in our ability to achieve the vision of a truly interoperable and fully useful electronic prescribing environment that serves as a foundation for the larger NHII effort. Such an identifier would need to be employed in a manner that leaves the patient in control of access to his or her information while still enabling future research and innovation.

We agree with the testimony the NHII Subcommittee of NCVHS heard last week from the Markle Foundation, which recommended against the creation of a National Patient Identifier (issued and maintained centrally), and instead support the creation of a voluntary, standardized method for issuing identifiers that uses a federated approach for linking these identifiers. We ask that the Subcommittee recommend the creation of a patient identifier infrastructure that serves this greater purpose.