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Oral Presentation

Prescription Drug Importation Public Meeting (Docket No. 2004N-0115)

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**Oral Presentation – HHS Task Force on Prescription Drug Importation Public Meeting
(Docket No. 2004N-0115) April 14, 2004 – Tom Curb, R.Ph.**

My name is Tom Curb. I have been a registered pharmacist for 41 years – with more than 38 dedicated to aspects of managed pharmacy benefits relating to hospitals, HMOs, PBMs, retail pharmacy networks development, prescription claims processing, pharmaceuticals purchasing, and as an independent consultant on matters pharmaceutical. My background and experience qualify me to make the following comments and observations.

The challenge before this commission is to assess the potential for a cost-effective and safe system for the importation of Canadian prescription drugs. Obviously, the most expedient solution to correct U.S. drug price inequities would be adjustment of prices to parallel those of other developed countries. The next most equitable would allow American drug wholesalers and retail pharmacies to import bulk medications from international sources. In today's environment, neither will happen; therefore, American consumers must look to direct personal importation to circumvent the predatory pricing of the international drug cartel.

I will describe such an importation program with documented cost-effectiveness and patient safety. First, necessary elements must be defined and addressed.

Lower Drug Cost – a “given”:

Informed Americans know they can obtain cheaper drugs from outside the US. Historically, because of the federal government's openly permissive stance on personal importation, border-state Americans crossed into Canada or Mexico and returned with their medications - and even some of their money. With the emergence of web-based pharmacies; escalating US drug prices; and publication of the government's “humanitarian” position on enforcement of antiquated and protectionist drug import laws, beleaguered and financially-strapped Americans once held hostage to their geography flock to their mail boxes to realize huge savings on their medications.

Effectiveness and Safety: *Appropriate therapeutic response and patient safety demand two primary considerations: Product efficacy and real-time electronic safeguards – the former being affected by accountability of source and the latter by applications of proven technological edits.*

Product Efficacy:

Dirre government and industry predictions about unsafe or “substandard” drugs from licensed Canadian pharmacies have proved invalid. Documentation of more than 38,000 “Canadian-sourced” prescriptions subjected to the below-described safeguards reveals that there were no reports of counterfeit drugs, sub-standard drugs, or adverse drug events. (These statistics are especially important because the majority of patients had affiliated medical benefit programs and thus were subject to consistent and routine physician oversight.)

Real-time Electronic Safeguards:

Although there is no validated evidence of product-related death or injury to Americans importing drugs from licensed Canadian pharmacies, tens of thousands of patients obtaining drugs from within the U.S. system die or are seriously injured from adverse drug events. To

help prevent these, U.S. pharmacists are required to maintain patient profiles (drug utilization histories) that interface real-time with technology that identifies potential medications-related problems. Also, prescription benefits managers (PBMs) require claims processors to maintain a central profile of each member's drug utilization within the provider network and for the profile to be linked to similar patient-protective technology.

The primary purpose for these patient-protective technologies is the prevention of adverse drug events caused by drug-to-drug interactions - an essential deterrent for which is a comprehensive patient profile. Obviously, even within the internal U.S. system, applications of these patient protective measures are not universal. Many Americans do not consistently trade at one pharmacy, and an "out-of-network" situation will occur if a customer obtains a prescription from a non-technologically linked pharmacy or if a prescription is not submitted to a PBM's claims processor. ***An out-of-network prescription permanently contaminates the patient's profile with respect to that medication and all subsequent medications. Without appropriate technological monitoring, imported prescriptions will also meet this out-of-network criterion.***

Increasing public awareness of cheaper foreign drugs and ease of acquisition via the Internet caused perceptive healthcare providers to recognize an eminent danger to their members' health from potential out-of-network prescriptions. To alleviate risks due to omission of data about imported drugs from members' drug histories, and ***in an effort to fulfill their mission to protect members' health (and in many cases the plans' resources) proactive benefit plans took preemptive action to incorporate proven patient protective measures into benefits designs.***

Also recognizing the danger from data omission in customers' drug profiles, visionary retail pharmacists have tried to fill that obvious void. Facing a threat of reduced revenues, they offered to supplement their in-house patient profiles with imported drug data; to inform their "importing" customers of safer mechanisms; to advise them on relative costs of domestic versus imported medications; and to answer customers' questions about the products that they may choose to import. (Regarding revenue loss, a North Carolina pharmacist replied, ***"I don't care. I'm tired of taking 50 to 75% of an elderly customer's social security check and passing it on to a drug company based in China, Japan, England, Germany, Switzerland, etc. that charges Americans more for their products than anyone else in the world!"***)

I emphasize this technological aspect of a "safe mechanism" because some regulators seem to misunderstand the process, or they underestimate its importance. Despite the irrefutable need for these universally-acclaimed and professionally-endorsed safeguards, and ignoring evidence that the lack thereof is a much greater threat to citizens than unsupported "product-related" concerns, the federal government, in concert with state officials and regulatory agencies, is attempting to prevent application of these safety measures to imported prescriptions. ***Hopefully theirs is not just another effort to placate a narrow but influential constituency, for by discounting the necessity of such measures, regulators will create a preventable, yet grave and imminent danger to American consumers.***

After misleading U.S. consumers, insurers and health care providers with what now appear to have been politically expedient statements and testimony relating to importation policy, government agencies are challenging benefit plan sponsors, administrators and retail pharmacies that try to provide these patient-protective processes. ***If regulators deny consumers access to these safeguards they will have abandoned their mission to protect Americans' health and instead create a deadly environment that is diametrically opposed to the safer one enabled by application of universally-endorsed and proven healthcare technologies.***

The Safe and Cost-Effective Canadian Import Mechanism:

Because U.S. price ceilings and bulk importation are not in the foreseeable future, the most viable, albeit a temporary solution is a personal importation program involving cooperation between Canadian and American regulators that will enable experienced professionals and healthcare entities within their respective countries to perform their services subject to easily defined and implemented guidelines. **These guidelines will assure *drug source accountability*; *multi-level oversight by qualified healthcare professionals*; and *imposition of appropriate technological safety edits*.**

1) Licensed Canadian pharmacies would be certified or “credentialed” subject to accepted professional criteria. Evidence of certification would be made available to American consumers desiring to import their personal medications as well as to U.S. healthcare providers and retail pharmacies.

2) In the absence of reciprocity and/or dual licensure, Canadian prescribers would be credentialed based on accepted professional criteria that would include “reviewer” requirements. (Canadian physician review can be a valuable *de facto* second opinion.) Evidence of prescriber certification would be made available to credentialed Canadian Pharmacies.

3) U.S. prescription benefit plans and/or their PBMs would be allowed to coordinate with credentialed Canadian pharmacies to obtain medical and drug data that have been supplied to them by their importing members and to electronically process Canadian prescription claims for those members.

3) U.S. retail pharmacies would be allowed and encouraged to establish cooperative relationships with Canadian pharmacies and/or U.S. PBMs that would enable them to become involved in their customers’ importation process. This would include: Incorporating imported drug data into the pharmacy’s patient profile and/or submitting customers’ prescriptions to a claims processor’s central profile that maintains that data; counseling customers as to the feasibility of importing specific drugs and about imported drugs they have received; and to offset their “lost revenue”, receiving a reasonable counseling fee for their services.

This mechanism is not a “pipe dream” or product of “wishful thinking” – it is immediately “do-able”. **The technologies, safeguards and processes to accomplish these programs have been developed; prototypes can be demonstrated; and positive results validated. *There is no basis for argument that an imaginary geographic divide will prevent the imposition of these proven patient-protective processes* – and, *for those previously-referenced 38,000 prescriptions, the “Canadian” savings were in excess of 6 million dollars when compared to already reduced prices in a U.S. pharmacy network– an average savings of more than \$150 per prescription (>50%).* The U.S. government did not invest a single nickel to achieve these savings.**

These dollar amounts reveal the degree to which current U.S. government policies force American consumers to subsidize the international drug cartel, and with implementation of the funded Medicare drug “benefit”, non-consuming U.S. taxpayers will also be subjected to this government-imposed “healthcare tax”.

Congress has specifically asked HHS to consider the following issues:

1) *Impact of unapproved drugs:* “FDA unapproved” designation is not a valid indicator of

drug quality or of therapeutic efficacy. It is a misleading designation used to imply that some “imported” drugs may be inferior to those obtained in the U.S. For instance, *even if a specific drug entity may be available and approved by the FDA for use in the US and may come from the same manufacturer source and may be exact in content, composition, therapeutic effect, and formulation, the imported product can be designated by the FDA as “unapproved” for reasons as insignificant as a difference in the appearance of the drug (color, shape, form); the wording on the container’s label; the type of container the drug is in; or even the way the container is closed.*

Scope and volume: (See “unapproved” above) **Many brand name drugs are not economically feasible for importation. Canadian generics for drugs that also have generic equivalents available in the U.S. offer no economies.** Prescriptions for these and all controlled substances, perishables, and immediate-need drugs would be filled by U.S. retail pharmacies. *Even at improbable full participation, less than 10% of U.S. brand name prescriptions would be feasible for importation.* (The aforementioned 37,000 “Canadian” prescriptions comprise less than one-half of one percent of “ambulatory” brand name prescriptions that were concurrently processed.)

Safety concerns: **The credentialing process described enables accountability of sourcing;** therefore, *safety concerns are only those that may be created by government agencies in preventing imposition of patient-protective technological edits.* Also, documentation of product safety herein is evidence that product-related concerns are overstated and invalid.

2) **FDA’s ability to assure safety:** **This personal importation scenario will significantly reduce the need for constant oversight.** Credentialing and source accountability allowed by an easily monitored Canadian drug-acquisition trail minimize the need for inspections. Also, *by allowing a terminal, hands-on medications expert – the U.S. retail pharmacist – to intervene in a customer’s importation process, the government would recruit a nation-wide network of willing, concerned and dedicated professional experts – at no taxpayer cost.*

3) **Regulatory/Legislative issues:** **Regulations and laws should be flexible – they need to be modified with progress and evolving conditions.** Product safety and FDA approval re: imported drugs are addressed above. Due to drug counterfeiting found within the U.S., the real problem before the FDA is *“How can FDA assure the same level of safety for drugs purchased at a (U.S.) state-licensed pharmacy as can be expected from a Canadian-licensed pharmacy?”*

4) **Technology: Re: Counterfeiting – currently proposed efforts to prevent counterfeiting are cosmetic and costly, and they will invariably prove to be ineffective.** Counterfeiters can package in unit-dose, and they can print bar codes, etc. *The most effective deterrents to counterfeiting are accountability for drug source, equitable pricing, and multi-level professional oversight – all of which are addressed in the above-described importation scenario.* So long as the huge discrepancy exists between U.S. and international prices, the internal U.S. distribution system will be a target for counterfeiters simply because therein lies their greatest profit potential - *crooks do not counterfeit dollar bills – they counterfeit twenties.*

5) **Financial impact on:**

Drug prices – Importing U.S. consumers’ prescription prices would drop immediately and significantly. In the long term, they would stay down, and because of forced competition between manufacturers comprising the international drug cartel, costs for all U.S. consumers would evolve to more nearly match lower international prices. Also, because of a

potential Canadian “safety valve”, there would be a reduced incentive for manufacturers to establish artificially high U.S. prices by cornering markets on product ingredient.

Drug manufacturers – In the short term, some in the international drug cartel will still conspire to limit drug importation into the U.S. There is a collective greed within the drug industry that lets it unite to impose price-fixing measures – as with Glaxo, Pfizer, and Lilly; however, a stronger intrinsic and individual greed resides within each member of the cartel that encourages it to use any opportunity to gain marketing advantage over its competition. ***Individual manufacturer greed will eventually break manufacturers’ supply boycotts. The international drug cartel understands the old adage that “50% of something is better than 100% of nothing”.*** Example: A manufacturer-imposed Canadian pharmacy shortage of Zoloft will be offset by consumer gravitation to Lexapro, Paxil, generic fluoxetine, etc. The same would apply to the effect of a Celebrex “shortage” that would be filled by Vioxx or even older NSAIDs that are just as effective and cost much less.

Some manufacturers that are thereby relieved of expensive U.S. marketing costs would welcome an indirect marketing advantage of a Canada to U.S. pass-through. *If truthful, a manufacturer would be glad to sell its products to anyone at Canadian prices* - especially since they would not be subject to the U.S. “best price” regulations, which along with “most favored nation” rules limit price competition in the U.S. through governmental “pegging” of drug prices above those achievable in a free market. (Before imposition of these government price “standards”, as a contracting agent for pharmaceuticals’ purchases, I had manufacturers compete vigorously for the opportunity to sell their brand name products for as little as a “dime on the dollar – or less.” It is a paradox that the U.S. condemns drug price “ceilings” imposed by other nations, but it is the only developed nation to impose artificially high drug price “floors” that prevent establishment of a free-market for drugs through competitive negotiation.)

Therefore, in the long term, because of the plethora of “me-too” drugs, manufacturers’ quantity limitations to Canadian exporting pharmacies will provide incentive for intrinsic greed to take over, thereby encouraging consumer movement to therapeutic alternatives. It is probable that manufacturers profiting from a “Canadian pass-through” would increase product shipments to Canada; however, if Canadian supplies could not support a large influx of U.S. prescriptions, a program of the above design could easily be serviced from anywhere in the world.

U.S. Pharmacies – In the described scenario, participating U.S. retail pharmacies would realize more net profit per prescription from Canadian “consulting fees” than they do from sale of the affected brand name drugs, and they would be relieved of stocking expensive medications and ancillary costs of prescription dispensing. They would retain all prescriptions for generics (which are their greatest profit generator), controlled substances, environmentally sensitive, and acute and immediate need drugs. ***An important fringe benefit would be that their customers would have hundreds of extra dollars that could be spent in the local community rather than being passed on to the international drug cartel.***

Wholesalers – American wholesalers consistently claim that they do not profit from handling brand name drugs. It is relatively easy for a retailer to buy brands from the wholesaler at “Wholesaler Acquisition Cost” minus 2%. If U.S. wholesalers are truthful, Canadian importation should not impact them at all.

System costs – In the above-described scenario, there would be minimal or no costs accruing to the government - the program would be self-funding.

Research and Development – Consumers worldwide would benefit immensely. The international drug cartel would be challenged to direct research toward new and unique products rather than using minor molecular manipulations to generate U.S. market oriented “me-too” products. Can one justify U.S. need for 30 combination oral contraceptives; a dozen beta blockers; twenty channel calcium blockers; a dozen ace inhibitors; nine (and still coming) anti-cholesterol drugs; a half-dozen proton pump inhibitors; seven SSRI’s and Heaven only knows how many more products to treat the “ominous” effects of erectile dysfunction?

There would be less incentive for manufacturers to exploit U.S. rules that allow re-establishment of patent protection for resurrected “ancient” chemical entities previously available as inexpensive generics. Because of government sanctioned “new drug approvals”, decades old products like guaifenesin and levothyroxine now cost ten to twenty times their previous generic prices. (Historically, with minor, irrelevant physical or cosmetic manipulations, drug entities such as nitrofurantoin and propoxyphene were enabled to maintain patent-protected and costly sole-source status for decades beyond what should have been allowed.)

Liability – With pharmacist and physician credentialing and source accountability, there would be no additional liability concerns.

Foreign “regulatory” agencies – This is an irrelevant question. If other countries do not already have protections that ensure the safety of drugs that are exported or transshipped from their country for U.S. consumption, then the American consumer is already in grave danger. National allegiance or origin does not apply to pharmaceuticals’ production. Most major drug manufacturers are international conglomerates based in Europe and Asia with manufacturing facilities all over the globe. ***In fact, 9 of the top 10 (90% of) brand name drugs by volume and cost processed through SPC for benefit plans’ members were manufactured outside the US. All have been “FDA-approved” for US consumption.***