ONE HUNDRED EIGHTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON GOVERNMENT REFORM

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September 28, 2004

The Honorable Tommy G. Thompson
Secretary of Health and Human Services
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Mr. Secretary:

I am writing regarding a potentially significant health risk that seniors could face due to the new Medicare drug law: unsafe copies of brand-name and generic prescription drugs made by compounding.

The Bush Administration has aggressively worked to keep lower-priced imports from America's seniors because of professed concerns about the safety of Canadian drugs, which have not been approved as safe or effective by the Food and Drug Administration (FDA). Indeed, just last month FDA threatened legal action against state programs to reimport foreign drugs for their citizens.[1]

At the same time, however, it appears that under the new Medicare law you are establishing a system that would allow many prescriptions for FDA-approved products to be filled with copies that, like imported drugs, have not been approved by FDA. These copies are made through compounding, a process where pharmacists manufacture the drugs themselves, without FDA oversight. Inappropriately compounded drugs have been shown to be unsafe, causing numerous adverse events, including several fatalities. Yet you are allowing these drugs to be sold to the same Medicare beneficiaries you are preventing from purchasing reimported drugs.

The Risks of Pharmaceutical Compounding

Pharmaceutical compounding involves the creation of drugs in small-scale or individual quantities from raw ingredients. In some cases, compounding is medically necessary. For example, physicians may rely on compounding pharmacies to create new dosage forms that are tolerable for young children and others who cannot take the FDA-approved dosage forms. When

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[1] CBS MarketWatch.com, *FDA May Sue over Drug Imports* (Aug. 25, 2004).

done responsibly and in small quantities, the risks of compounding are outweighed by their important benefits to patients.

However, there are other compounded drugs that do not serve an unmet medical need, but are simply copycat versions of FDA-approved drugs. Like imported drugs, the sole benefit offered by these copycat drugs is a potentially lower price. Unfortunately, these copycat drugs can pose serious risks to the public. Unlike the FDA-approved drugs, these copies are not evaluated by FDA for safety and efficacy. Their manufacturing facilities are not inspected for cleanliness, hygiene, or adherence to accepted methods of drug manufacturing. And their quality can be substandard. A small-scale study by FDA in 2003 found that over one-third of compounded drugs failed to meet basic standards of quality. [2]

Because compounding pharmacies are not being required to follow regulations such as good manufacturing practice regulations and requirements with regards to labeling, compounded "copies" of approved drugs can pose three serious health risks to seniors:

- Failure to ensure sterility. Compounding pharmacies can sell drugs that are required to be sterile by FDA, but in fact are contaminated with life-threatening pathogens. A common example of this problem can be found in respiratory drugs, such as nebulizer solutions used to treat asthma and chronic obstructive lung disease. In the past three years, thousands of patients have received compounded respiratory drugs contaminated with life-threatening bacteria.[3]

- Failure to deliver the appropriate dose. Compounded "copy" drugs can actually provide more or less of the drug substance than intended by the physician. If too much is delivered, there is a danger of overdose and toxicity. If too little, there is a danger of undermedicating the senior's condition. In 2001, several Georgia women were hospitalized after receiving excessive thyroid hormone from a compounded copy of the drug.[4] The 2003 study by FDA found that one-quarter of all compounded drugs were subpotent.[5]

- Failure to provide accurate labeling information. Compounding pharmacies offer products made with the same ingredients as existing drugs but without key information

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[2] U.S. Food and Drug Administration, *Report: Limited FDA Survey of Compounded Drug Products* (Jan. 28, 2003).

[3] *Missouri Officials Begin Tracking Contaminated Drug*, Kansas City Star (Mar. 13, 2003); *Respiratory Update,* Pharmacy Compounding (Sept. 2003).

[4] *Probe Questions Safety of Pharmacy Made Drugs*, Atlanta Journal-Constitution (Mar. 30, 2001).

[5] U.S. Food and Drug Administration, *supra* note 2.

and warnings required by FDA. This is a particularly important problem for seniors, because many seniors take multiple drugs, increasing the risk of harmful interactions.

The risks to consumers generally, and to seniors specifically, from inappropriately compounded drugs are serious. There is no systematic surveillance of problems with compounded drugs. But a 2002 review by the U.S. General Accounting Office found that, based on voluntary reporting, media reports, and other sources, FDA has become aware of over 200 adverse events caused by compounded drugs since 1990.[6] These adverse events included three deaths and 13 hospitalizations.[7]

Medicare Has Driven the Growth of the Drug Compounding Industry

One of the primary reasons for increased sales of compounded drugs in recent years is the fact that Medicare currently pays for some of these drugs. The Medicare program at present pays for a limited number of drugs under Part B of the program: generally, those that either cannot be self-administered (such as cancer drugs) or those that require additional medical equipment to administer (such as respiratory drugs that require nebulizers).

This latter group of drugs has attracted numerous compounding pharmacies into the Medicare market. These compounders create copies of FDA-approved drugs that are on the Medicare reimbursement list. Because compounding pharmacies can purchase the raw materials to make these copies at low prices, while receiving reimbursements from the Medicare program based on the price of the FDA-approved product, there is a tremendous financial incentive for these pharmacists to compound the drugs for sale to Medicare beneficiaries.

According to experts on pharmaceutical compounding, "reimbursement under Medicare has served as a primary driver of the contemporary compounding industry."[8]

Current Medicare policy for payment of drugs under Part B is that the program will cease payment for compounded drugs only if "FDA has determined that a company is producing compounded drugs in violation of the FFDCA. [In these cases] Medicare does not pay for the drugs because they do not meet the FDA approval requirements."[9] In other words, Medicare

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[6] General Accounting Office, *State and Federal Oversight of Drug Compounding by Pharmacies* (Oct. 23, 2003) (GAO-04-195T).

[7] *Id.*

[8] Sarah Sellers, *Not All Drugs Are Created Equal: The Emerging Pharmacy Compounding Industry*, John Hopkins Bloomberg School of Public Health (June 2004).

[9] CMS, *Medicare Benefits Policy Manual,* Denial of Medicare Payments for Compounded Drugs Produced in Violation of the Federal Food, Drug, and Cosmetic Act, 50.4.7 (2004).

will refuse payment for a compounded drug only in the unusual circumstance that FDA has specifically found that a particular compounding pharmacy is violating federal law. These provisions, which rely solely on FDA's limited and vague enforcement capacity (which is further hampered by a lengthy enforcement process),[10] are clearly doing little to discourage pharmacy compounding.

The New Medicare Drug Benefit Is Likely to Lead to Increased Use of Potentially Unsafe Compounded Drugs

Unfortunately, I am concerned that CMS appears poised to repeat past mistakes with regard to Medicare and compounded drugs. If so, the new Medicare drug benefit could ultimately result in a significantly increased use of unregulated and potentially unsafe compounded drugs by seniors.

Although the drug program will be administered by private pharmacy benefit managers rather than directly by CMS, the basic problem will remain: CMS will allow pharmacy benefit managers to reimburse Medicare beneficiaries for compounded copies of FDA drugs. Because these drugs can be sold at prices that are lower than the original, FDA-approved manufactured drug, consumers who are unaware of potential safety issues will have a direct financial incentive to purchase these unapproved, potentially unsafe compounded drugs.

On July 26, 2004, CMS released its proposed rules for the Medicare drug benefit.[11] It appears that these proposed rules would allow compounding of prescription drugs for Medicare beneficiaries, both in cases where the compounding is medically necessary because the drugs are not manufactured in the required form, and in cases where the compounding is unnecessary, such as the production of copies of FDA-approved products from raw ingredients.

The proposed rules state that drugs will be covered based on "approval by the Food and Drug Administration."[12] This language is similar to the language currently in place for coverage of drugs under Part B, and would presumably be interpreted in a similar fashion: allowing PBMs to pay for compounded drugs unless FDA has affirmatively found the drug compounder to be in violation of the FFDCA. Given the failure of the existing provisions to eliminate dangerous compounding under Part B, it is unlikely that these new provisions will be any more effective at eliminating dangerous compounding in the new Medicare drug benefit.

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[10] *See* General Accounting Office, *supra* note 6.

[11] CMS, *Proposed Rule: Medicare Programs: Medicare Prescription Drug Benefit* (July 26, 2004) (online at www.cms.hhs.gov/medicarereform/mmaregions/CMS4068P.pdf).

[12] *Id.* at 86.

Conversations by my staff with CMS staff responsible for the proposed rules have confirmed this interpretation. CMS staff have indicated that if the active ingredient in a compounded drug is FDA-approved, Medicare would allow reimbursement for the compounded drug.[13]

A Company Affiliated with Medicare Drug Discount Cards Is Already Participating in Potentially Dangerous Drug Compounding

These concerns have been exacerbated by the fact that at least one company that runs a Medicare-approved drug discount card is already engaging in potentially unsafe drug compounding. NationsHealth, L.L.C., in conjunction with Wellpoint Pharmacy Management, is currently offering seniors a Medicare-approved prescription discount card (this card is sold as the PrecisionDiscounts card).[14] The NationsHealth website indicates that "NationsHealth is a leading provider of Medicare Part B services for persons with diabetes or respiratory conditions. Over 60,000 Medicare beneficiaries receive their diabetes or respiratory supplies when they need them from NationsHealth, conveniently and discretely."[15]

Recently, Sarah Sellers of the Johns Hopkins Bloomberg School of Public Health obtained a prescription form from NationsHealth that indicates that the company is currently filling a number of prescriptions for Medicare Part B drugs with compounded medications.[16] Ms. Sellers, a pharmacist and member of FDA's advisory board on drug compounding, provided this document to my staff, a copy of which is attached. This document shows that NationsHealth is offering several popular medications used to treat asthma, emphysema, and other breathing conditions with notations that indicate that the medications will be compounded. In the case of albuterol sulfate, for example, the prescription form includes notations specifying the size and strength of the dosage, as well as listing the inert solvent (in this case, a saline solution) as an ingredient.[17] According to Dr. Sellers, these notations are generally understood by physicians and pharmacists — although not by consumers — to indicate that a medication will be compounded.

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[13] Craig Miner, CMS, Telephone conversation with Committee on Government Reform minority staff (August 26, 2004).

[14] *See* PrecisionDiscounts Card website at https://precisiondiscounts.com/index.html.

[15] NationsHealth, *Medicare Part B Services* (2004) (online at www.nationshealth.net/partb.html).

[16] NationsHealth, *Prescription: Respiratory Medicines and Supplies* (2004).

[17] The dosage of albuterol sulfate is listed as 3 ml of a 0.083% solution, which is to be made by mixing 0.5 ml of a 0.5% albuterol sulfide mix with 2.5 ml of Normal Saline. Other medications listed on the form in a similar fashion include albuterol sulfate and ipratropium bromide; ipratropium bromide; and cromolyn sodium).

Conclusion

The Administration has aggressively acted to ban imports of prescription drugs, arguing:

> consumers are exposed to a number of risks when they purchase drugs from foreign sources . . . These outlets may dispense expired, subpotent, contaminated or counterfeit product, the wrong or a contraindicated product, an incorrect dose, or medication unaccompanied by adequate directions for use. . . . The drugs may not have been packaged and stored under appropriate conditions to avoid degradation. There is no assurance that these products were manufactured under current good manufacturing practice (GMP) standards.[18]

What is ironic is that the same problems apply to compounded drugs, yet CMS is poised to allow these compounded drugs to be provided to seniors through the new Medicare drug benefit.

While some compounded drugs — such as drugs which are simply not manufactured in the dosage or form needed by a given patient — may be necessary, many are not. Of particular concern are instances where compounding pharmacies are making copies of drugs that are manufactured and approved by FDA in identical forms and dosages. There is no public health rationale to allow such compounding.

In light of these concerns, I am requesting that:

(1) CMS determine whether seniors are currently receiving potentially unsafe compounded drugs offered by Medicare discount drug card sponsors, and if so, develop regulations to ensure that this practice is not continued.

(2) The new Medicare drug benefit rules under development by CMS disallow Medicare coverage under Part D for prescription drugs that have been compounded, unless the only way a drug is available in a required form is via compounding.

(3) The new Medicare drug benefit rules under development by CMS ensure that if seniors receive compounded drugs, they are aware that they are receiving a product that has not been approved as safe and effective.

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[18] Statement of William K. Hubbard, FDA Associate Commissioner for Policy and Planning, before the House Committee on Government Reform, Subcommittee on Human Rights and Wellness, U.S. House of Representatives (June 12, 2003).

Thank you for your attention to this request. If you have any questions, my staff contact on this issue is Brian Cohen at (202) 225-5051.

Sincerely,

Henry A. Waxman
Ranking Minority Member

NationsHealth

- Prescription -

Respiratory Medications and Supplies

Any fields pre-filled reflect your previous written prescription, or were confirmed verbally with your office by our pharmacist

Instructions: **Please fill in ALL Sections** and fax back **toll free to 1(800) 977-0601**

If you have any changes, please cross out, write in correction, sign and date form.

Toll Free Fax # 1(800) 977-0601

RID=000000061798

PATIENT [redacted]

Phone: [redacted]

HICN: [redacted]

Birth date: [redacted]

Our ID #: [redacted]

PHYSICIAN [redacted]

Phone: [redacted]

Fax #: [redacted]

Start Date: _____ (as confirmed with office, if none then date signed)

1 **Check Appropriate Diagnosis:**

☐ 496 COPD ☐ 492.8 Emphysema ☐ 491.9 Chronic Bronchitis ☒ 493.90 Asthma

☐ 786.4 Persistent pulmonary secretions-abnormal fluid (Acetylcysteine prescriptions only)

2 I am prescribing a Compressor Nebulizer E0570 unless otherwise noted below:

3 **Supplies** Please send: (one only) Disposable Nebulizer Tubing w/ Mask **OR** the Nebulizer option checked below

☐ Non-Disposable Nebulizer Tubing with Mask

☐ Tracheotomy Collar w/ Nebulizer ☐ **Other** _____

4

☐ **ALBUTEROL SULFATE 0.083% 3mL UD 0.5 mL Albuterol 0.5% IN 2.5mL Normal Saline**

☐ **IPRATROPIUM BROMIDE (Atrovent) 0.02% IN 2.5mL Normal Saline UD**

Steroid Products:

☒ **ALBUTEROL SULFATE 0.083% IN 3mL Normal Saline & IPRATROPIUM BROMIDE 0.02% IN 2.5mL Normal Saline (Separate UD vials)**

☐ **CROMOLYN SODIUM UD 20mg/2mL Sterile Water**

☐ **BUDESONIDE (pulmicort) 0.25mg/2mL**

☐ **SODIUM CHLORIDE 0.9% 3mL/dose UD**

☐ **BUDESONIDE (pulmicort) 0.5mg/2mL**

☐ **ACETYLCYSTEINE 10% 4mL UD (For abnormal fluid diagnosis only)**

☐ **ACETYLCYSTEINE 20% 4mL UD (For abnormal fluid diagnosis only)**

* The listed choices are only some possible therapies and others may be clinically appropriate.

☐ **METAPROTERENOL 0.4% 2.5mL UD**

☐ **ALBUTEROL SULFATE 3.0 mg with IPRATROPIUM BROMIDE 0.5 mg/3ml (Premixed)**

☐ **METAPROTERENOL 0.6% 2.5mL UD**

5 **Times Per Day Treatment:** (MUST check ☑ one) ☐ QD ☐ BID ☐ TID ☒ QID ☐ Q4H ☐ Other (Medicare does not accept "PRN")

6 **If treatment regimen exceeds 4 times per day, Medicare requires a detailed explanation of the reason: (✓ all that apply)**

☐ Obstructed Airway (progressive inelasticity of the lungs) ☐ Crackling and Congestion in the lungs ☐ Pneumonia

☐ Obstructed Breathing (inflammation of bronchial tubes) ☐ Bronchial Spasms ☐ Wheezing _____

☐ Increased Asthmatic Breathing Difficulty ☐ Shortness of Breath ☐ Other: _____

If treatment regimen exceeds 8 times per day, this completed form must be accompanied by **a Letter of Medical Necessity** signed by the physician on his or her letterhead.

7 Medicare maximum allowed **duration of need** is 12 months. Duration of need 12 months or if not otherwise specified (NOS), then 12 months.

By my signature below, I authorize the use of this document by a licensed pharmacy as a dispensing prescription. I have considered the use of a metered dose inhaler (MDI) with and without a reservoir or spacer device and decided that, for medical reasons, it was not sufficient for the administration of the prescribed inhalation drug(s). I certify that the information contained herein is a true and correct verification of my verbal or written order and that my medical records support the medical need for the items prescribed. I will maintain for Medicare/insurance requirements this signed original document in the patient's medical record file for post-payment review/audit purposes.

8 Physician Signature [signature] Date 7/31/04 **9**

10 UPIN E27706, If UPIN is incorrect, correct UPIN here _____, print name _____