

Compounding in Comp

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First, do no harm

The Physician-Patient-Pharmacist Triad

Physician examines and diagnoses patient's complaint, and if appropriate prescribes a drug or treatment. No conflict of interest if physician does not profit from prescription.

Patient, free of any undue influence by the prescriber, takes prescription to the pharmacist of his/her choice.

Pharmacist fulfills prescription. As s/he has not influenced the prescriber's choice of drug, is also free of any conflict of interest.

What Are Compound Drugs?

“Compounding” is the preparation, mixing, assembling, packaging, or labeling of a drug

Typically used for patients with allergies, specific medical conditions/limitations, and children



USP standards

Sterile Preparation (795)

Non-sterile Preparation (797)



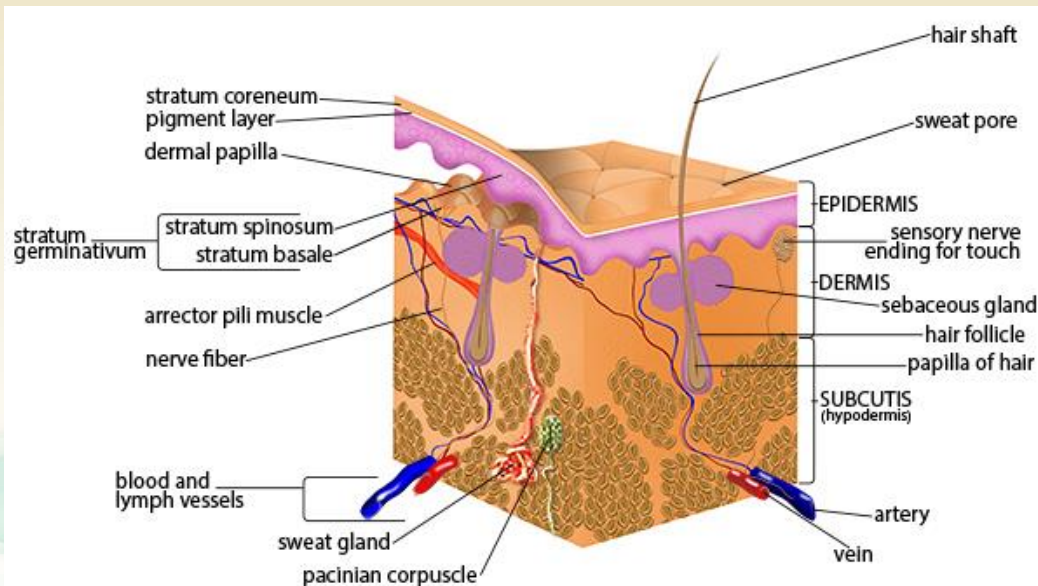
Types of Compounding

Examples

- sterile compounding of intravenous drugs for in-patient use
- compounding of oral preparations for individuals with allergies to ingredients found in manufactured drugs
- compounding of custom dosage forms of medications for patients with special needs

Problems: Not Proven Effective

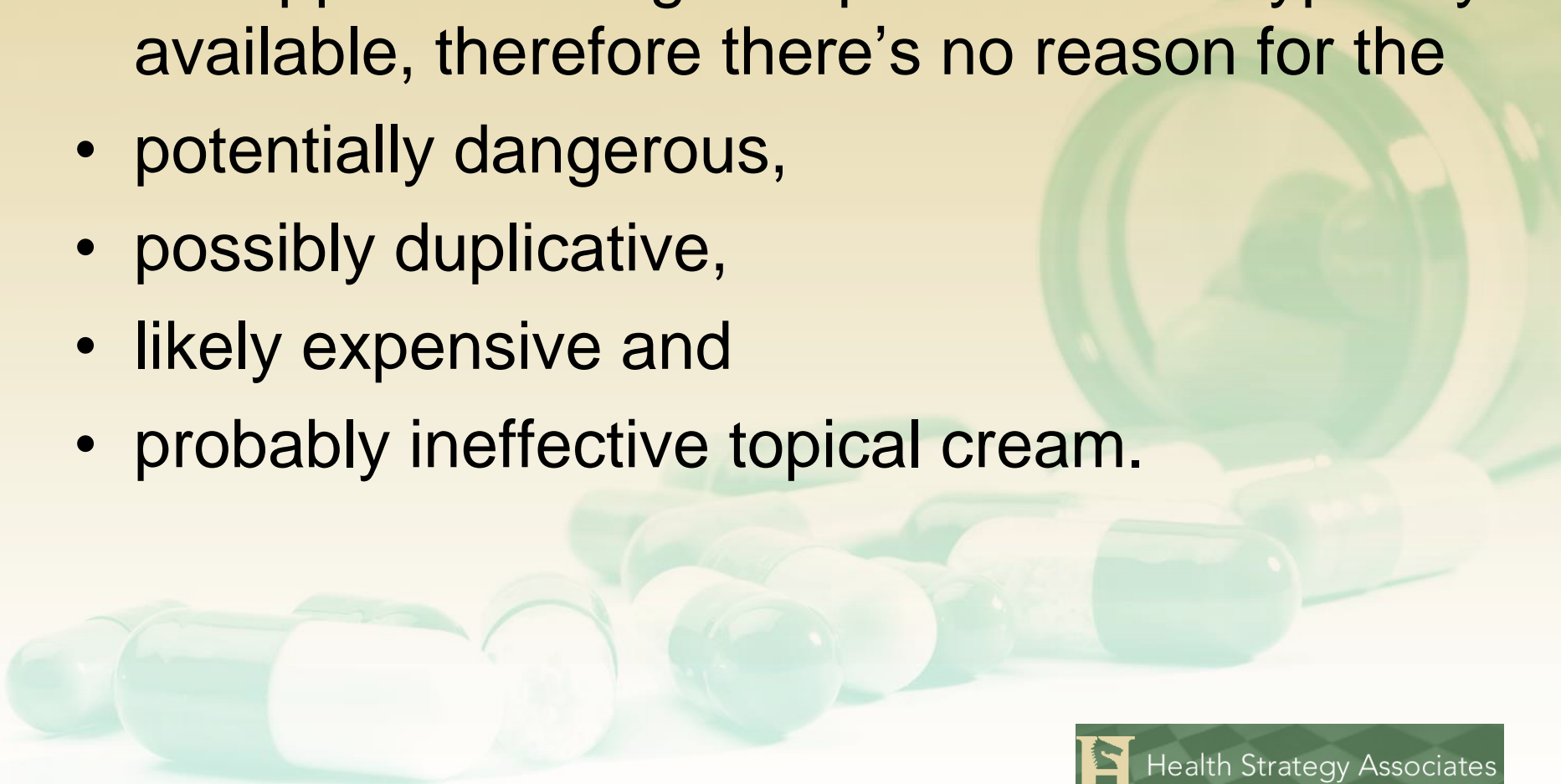
- Very little testing or oversight
- Not FDA approved
- Efficacy of drugs through dermal absorption has not been proven



Problems: Not Medically Necessary

FDA approved drugs in pill form are typically available, therefore there's no reason for the

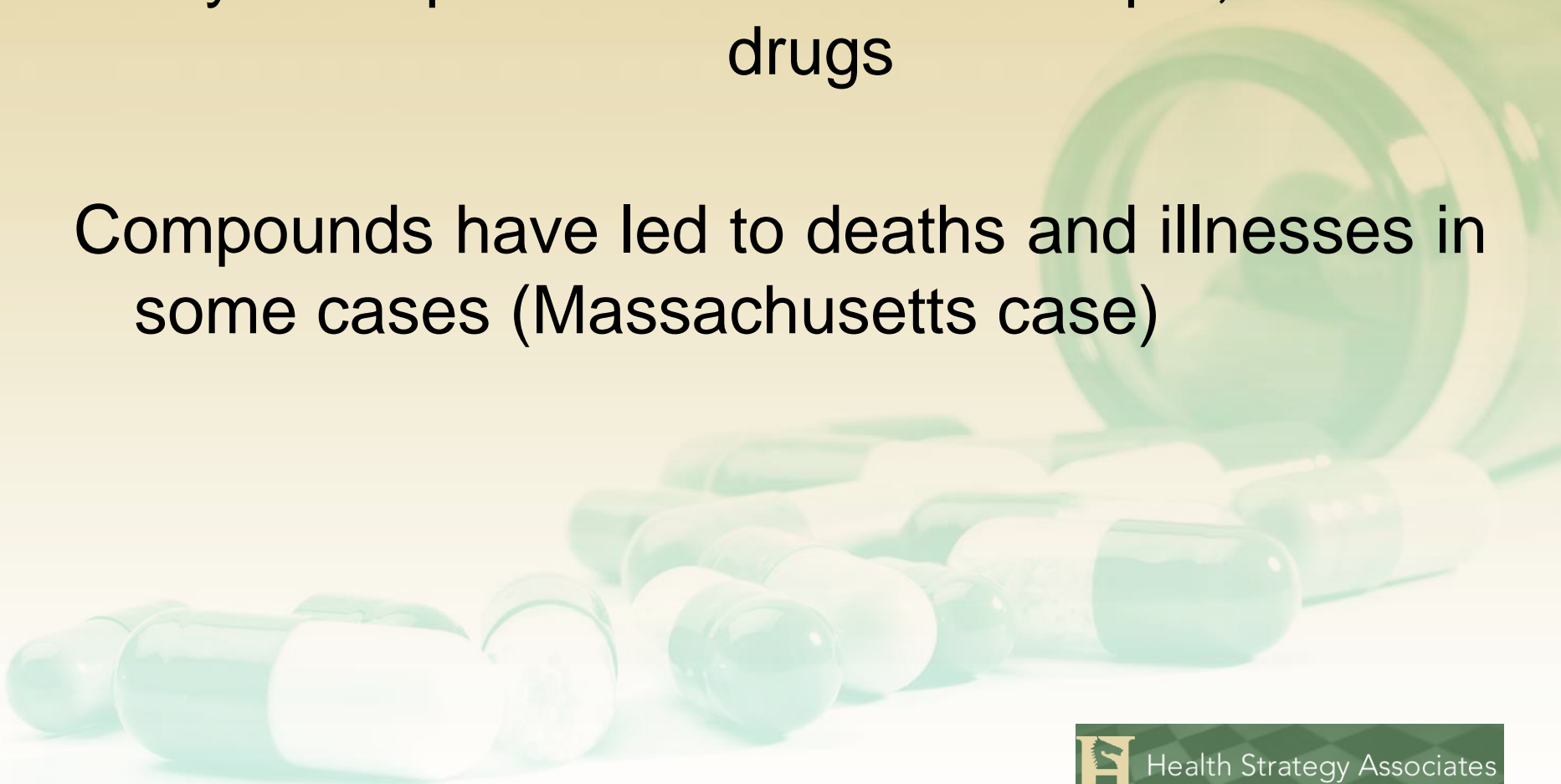
- potentially dangerous,
- possibly duplicative,
- likely expensive and
- probably ineffective topical cream.



Problems: Duplicative & Risky

Many compounds contain multiple, similar drugs

Compounds have led to deaths and illnesses in some cases (Massachusetts case)



Problems: Expensive

- Can cost thousands of dollars
- Many states have no effective controls or limits on
 - Prices or
 - Number of scripts
- Compounding industry adapts to many controls INSTANTLY

Questionable Marketing Practices

- Direct to consumer advertising
 - 1099 sales forces
 - Physician dispensing
 - “Detailing” prescribers
-
- Result: Egregious profits for many.

Mass Marketing

Compound Script

PLEASE INCLUDE PATIENT DEMO SHEET AND FRONT/BACK OF PATIENT INSURANCE CARD WITH THIS SCRIPT

Fax: _____

Patient Full Name _____ DOB _____ / _____ / _____

Address: _____ Best Contact Phone (____ -) _____

City: _____ State: _____ Zip: _____ Allergies: _____

Workers Compensation? Y _____ N _____ HMO / PPO? Y _____ N _____ Diagnosis Code: _____

INFLAMMATION

1. Musculoskeletal/Myofascial Pain-Tendonitis-Plantar Fasciitis-Arthritis-Epicondylitis
Flurbiprofen 10%, Diclofenac 10%, Gabapentin 10%, Lidocaine 5%

2. Tendinosis-Strictures-Scarring
Flurbiprofen 10%, Baclofen 2%, Verapamil 10%

NEUROPATHIC

3. General Neuropathy
Ketamine 10%, Baclofen 2%, Cyclobenzaprine 2%, Flurbiprofen 10%, Gabapentin 6%, Lidocaine 2%

4. RSD/CRPS-Trigeminal Neuralgia-Phantom Limb Pain-Developing Neuropathy
Ketamine 10%, Clonidine 0.2%, Gabapentin 6%, Imipramine 3%, Mefenamic Acid 3%, Lidocaine 2%

☐ 5. Chemotherapy Induced Peripheral Neuropathy-Diabetic Peripheral Neuropathy
Ketamine 10%, Baclofen 2%, Gabapentin 6%, Imipramine 3%, Mefenamic(?) 2%, Lidocaine 2%

COMBINATION

☐ 6. Musculoskeletal Pain-Inflammation
Ketamine 10%, Gabapentin 6%, Baclofen 2%, Cyclobenzaprine 2%, Lidocaine 2%, Flurbiprofen 10%

☐ 7. Radiculopathy-Fibromyalgia
Ketamine 10%, Baclofen 2%, Cyclobenzaprine 2%, Diclofenac 3%, Gabapentin 6%, Lidocaine 2%

☐ 8. Myofascial Pain Syndromes - TMJ
Flurbiprofen 10%, Baclofen 2%, Cyclobenzaprine 2%, Gabapentin 6%, Orphenadrine 5%, Tetracaine 2%

☐ 9. Myofascial Pain-Post Laminectomy-Greater Neuropathic Components
Ketamine 10%, Baclofen 2%, Cyclobenzaprine 2%, Flurbiprofen 10%, Gabapentin 6%, Lidocaine 2%

FOR OFFICE USE RXS

*Indicate cream(s) by checking box(es)

Quantity:

_____ 30 GM _____ 60 GM

_____ 90 GM _____ 120 GM

_____ 240 GM

Number or Units: _____

*Please remember prescriber information below with signature.

Quantity: 180 GM _____ 240 GM _____ OTHER: _____

SIG: Apply 1-2 GRAMS to affected area 3-4 times daily ALT SIG: _____

REFILLS: 1 2 3 OTHER: _____

Claims of efficacy

2 high potency NSAIDS → 1. Musculoskeletal/Myofascial Pain-Tendonitis-Plantar Fasciitis-Arthritis-Epicondylitis

2 muscle relaxants → 3. General Neuropathy

2 or 3 muscle relaxants → 6. Musculoskeletal Pain-Inflammation, 7. Radiculopathy-Fibromyalgia, 8. Myofascial Pain Syndromes - TMJ, 9. Myofascial Pain-Post Laminectomy-Greater Neuropathic Components

Examples

Houston, Texas: 4 residents were indicted on charges of conspiracy to commit wire fraud, and unlawfully distributing a controlled substance on 12/8/2015. The scheme ultimately resulted in \$17,000,000 in fraudulent healthcare claims over a two-year time period.

Florida

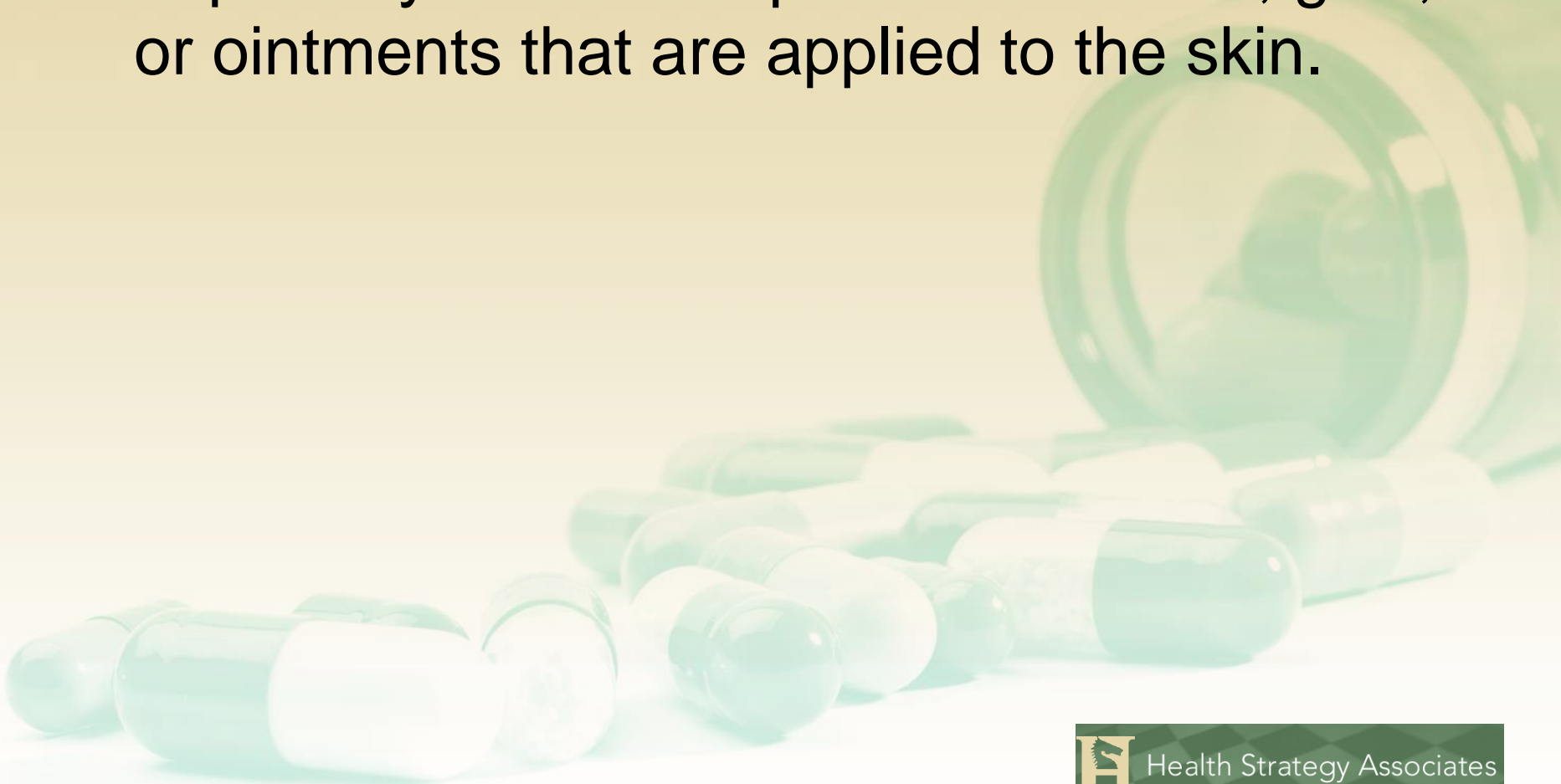
New Port Richey, FL: co-conspirators allegedly used A to Z Pharmacy Inc., located in New Port Richey, as well as several Miami-area pharmacies. The pharmacies allegedly submitted \$633 million in claims for compounded prescriptions and received \$157 million in payment.

Florida

Tampa, FL: the United States is seeking a money judgment in the amount of at least \$5.3 million as proceeds of the conspiracy and health care fraud offenses and forfeiture of a 2015 BMW in an indictment charging Dr. Anthony Baldizzi (52, Tierra Verde) with one count of conspiracy to defraud the United States, twenty-one counts of health care fraud, one count of money laundering, one count of making a false statement, and one count of receiving illegal kickbacks.

In Workers' Compensation...

The primary issue is “topicals” – creams, gels, or ointments that are applied to the skin.



Compounding Kits

The use of compounding kits (sometimes called FDA Convenience Kits) continues to increase. These kits are intended for topical use in the workers' compensation population, with various indications and may contain ingredients such as analgesics, muscle relaxants, steroids, anti-inflammatories or other drugs. These compounding kits are marketed to compounding pharmacies as a convenience to the compounding staff to save time, decrease waste and improve compliance, reproducibility and accuracy.

Compounding Kits (cont.)

Typically, these products are submitted by the dispensing pharmacy for processing through the PBM using the product NDC, rather than as a compound. This action bypasses the pharmacy-benefits managers and many state workers' compensation requirements for review of appropriateness of compounds. The use of compound kits by physicians likewise bypasses compound and other safety edits in place at the pharmacy.

FDA Regulation of Compounding

Compounding Quality Act, Title I of the Drug Quality and Security Act (DQSA) - Section 503A describes the conditions under which certain compounded human drug products are entitled to exemptions from three sections of the FDCA requiring:

Compliance with current good manufacturing practices (CGMP) (section 501(a)(2)(B));

Labeling with adequate directions for use (section 502(f)(1)); and
FDA approval prior to marketing (section 505).

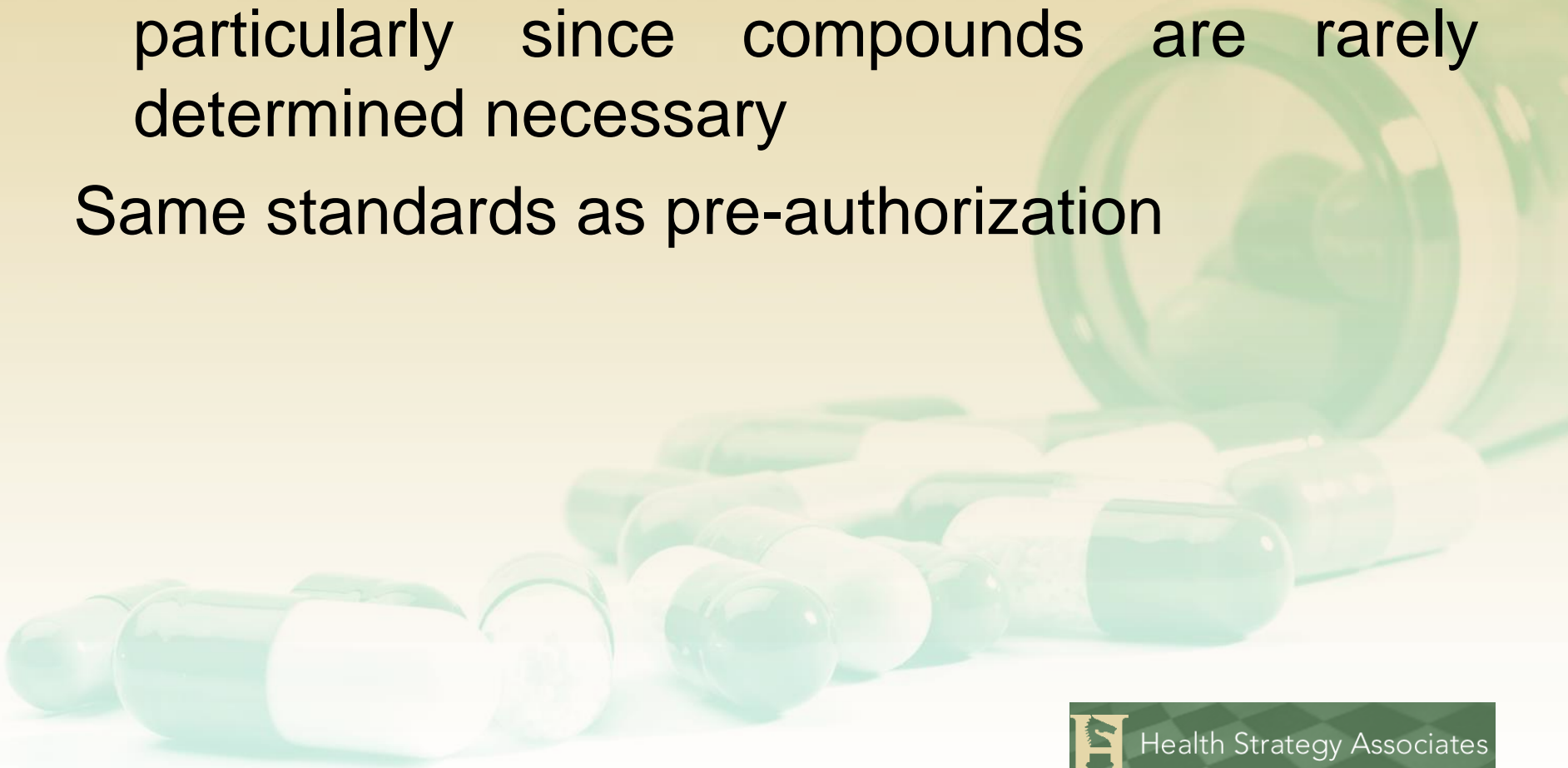
Potential Solutions - Reimbursement limits

- Per script
- Per ingredient
- Caps on number of ingredients, total cost per script
- Ohio's fix

Potential Solutions: Retrospective Review

Review for medical necessity post-dispensing,
particularly since compounds are rarely
determined necessary

Same standards as pre-authorization

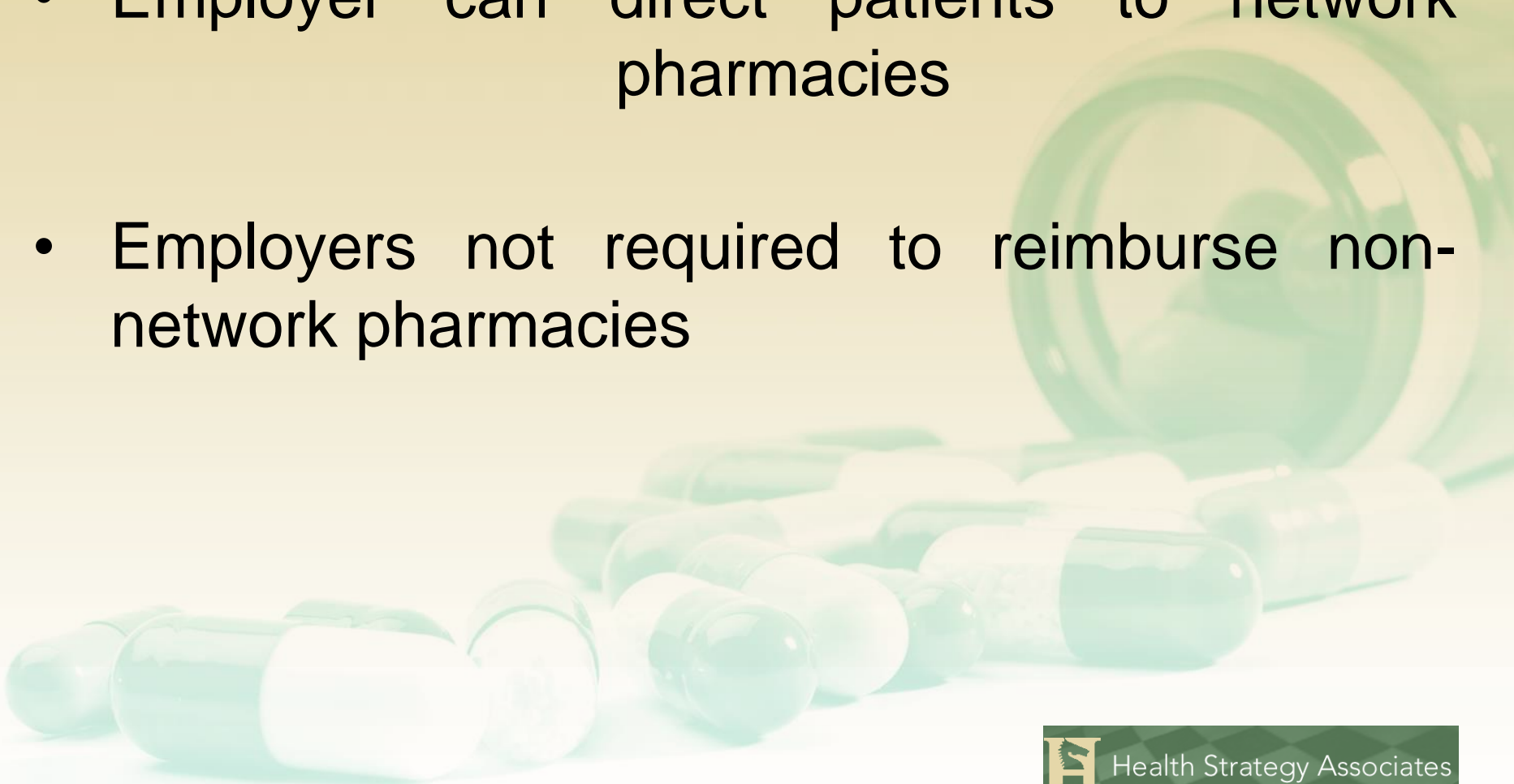


Potential Solutions: Pre Authorization

- All compounds must be pre-authorized by the payer
- Standard is compliance with Evidence-Based Clinical Guidelines (per state)
- Approval only if prescriber documents patient
 - Fails treatment with oral medications,
 - Is allergic to oral medication ingredients, and/or
 - Cannot swallow.

Potential Solutions: Employer direction

- Employer can direct patients to network pharmacies
- Employers not required to reimburse non-network pharmacies



Sources

- CompPharma.com
 - <https://comppharma.com/wp-content/uploads/2016/09/CompPharmaCompoundsinComp2017.pdf>
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