COMPOUNDED PAIN CREAMS

National Academies of Sciences, Engineering, and Medicine

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History of Compounded Pain Creams

Physicians looking for options for patients who were refractory to standards of care

- 1990's – Publications describing drug penetration, stability, and patient outcomes with Pluronic Lecithin Organogels (PLO)

- 2000's – Development of delivery vehicles to improve delivery profile of hydrophilic and lipophilic API
  - Also seek to improve chemical and physical stability of formulations and tactile properties
  - Validate vehicle performance via *in vitro* studies
  - Validate formulation compatibility and stability via stability-indicating assays

FDA-approved topical Diclofenac Sodium

Topical dosage (Voltaren 1% gel):
NOTE: The gel is only indicated for the relief of the pain of osteoarthritis of joints amenable to topical treatment such as the knees and hands. The gel was not evaluated for use on joints of the spine, hip, or shoulder.

Topical dosage (Pennsaid 1.5% Topical Solution):
NOTE: Pennsaid is indicated for the relief of the signs and symptoms of osteoarthritis of the knee(s) and was not evaluated for use on other joints.

For the treatment of actinic keratosis:
Topical dosage (3% gel):
Adults: Gently apply to affected areas twice daily. The amount needed depends upon the size of the lesion. Assure that enough topical diclofenac is applied to adequately cover each lesion (usually 0.5 g gel is used on each 5 x 5 cm lesion site). The recommended duration of therapy is from 60 to 90 days. Complete healing of the lesion(s) or optimal therapeutic effect may not be evident for up to 30 days following the cessation of therapy. Therapy may be interrupted for severe dermal reactions until the condition subsides.[62640]

NDC: 63481-0684-47

tube, 100 grams Diclofenac Sod 1%, Topical gel

Active Ingredients:	Diclofenac Sodium 1%
Drug Description:	white, opaque
Other Information:	Not Recommended for Splitting
Inactive Ingredients:	Ammonia
	carbomer 940
	Coco-caprylate/caprate
	Distilled Water
	Isopropyl Alcohol
	Mineral Oil
	Polyoxyethylene Alkyl Ethers
	Propylene Glycol

NDC: 75987-0040-05

bottle, pump, 112 grams Diclofenac Sod 2%, Topical solution

Active Ingredients:	Diclofenac Sodium 2%
Drug Description:	orange, pink, clear
Other Information:	Not Recommended for Splitting
Inactive Ingredients:	Alcohol
	Dimethyl Sulfoxide
	Distilled Water
	Hydroxypropyl Cellulose
	Propylene Glycol

NDC: 10337-0803-01

tube, 100 grams Diclofenac Sod 3%, Topical gel

Active Ingredients:	Diclofenac Sodium 3%
Drug Description:	colorless
Other Information:	Not Recommended for Splitting
Inactive Ingredients:	Benzyl Alcohol
	Distilled Water
	Hyaluronate Sodium
	Polyethylene Glycol

Annals of Internal Medicine®

ORIGINAL RESEARCH | 5 MARCH 2019

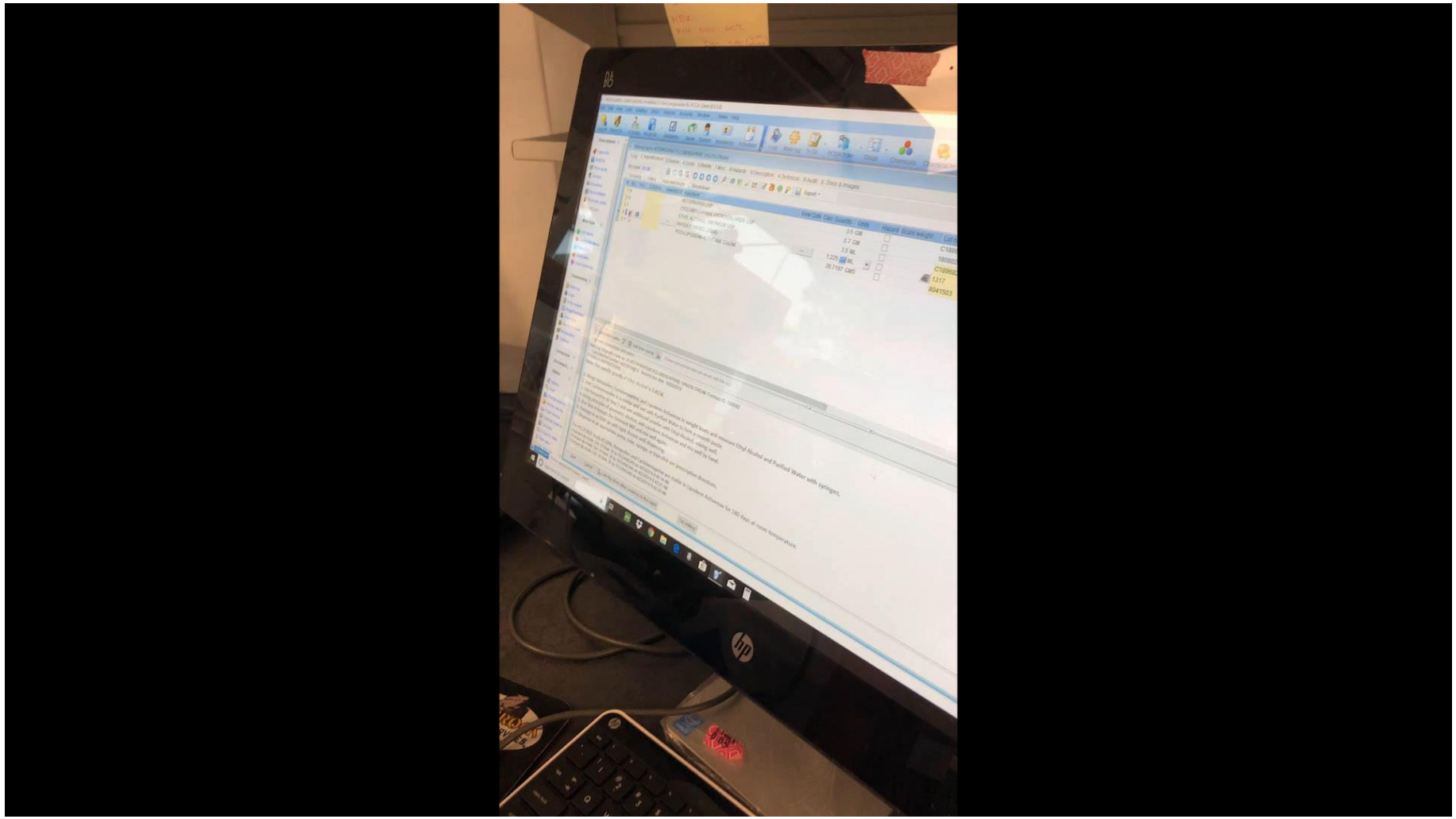
Compounded Topical Pain Creams to Treat Localized Chronic Pain: A Randomized Controlled Trial

Robert E. Brutcher, PharmD, PhD; Connie Kurihara, RN; Mark C. Bicket, MD; Parvaneh Moussavian-Yousefi, PharmD; David E. Reece, MD; Lisa M. Solomon, BS; Scott R. Griffith, MD; David E. Jamison, MD; Steven P. Cohen, MD

Patient Populations – The Bell Curve

- FDA approved products contain most of the API that are used in compounding, and serve most of the needs of the population
- FDA approved products are available in various routes of administration – oral, topical, injectable
- What is not addressed is the small percentage of the population that doesn't fit the mold of the mass-manufactured drugs
  - Patient compliance
    - Adverse reactions
    - Palatability or tactile issues
    - Convenience, particularly with multi-modal therapy
  - Specialized doses
    - Adjust dosing to optimize clinical outcomes, minimize adverse reactions
  - Intolerance to excipients

How Are Compounds Prepared? Video 1



How Are Compounds Prepared? Video 2

How Are Compounds Prepared? Video 3

How are compounds prepared?

- Compounding is NOT manufacturing

- USP <795> for compounded non-sterile preparations (CNSP)
- USP <797> for compounded sterile preparations (CSP)

- Pharmaceutical ingredients from FDA-registered and cGMP-inspected manufacturers
- Third-party analytical testing of compounds from FDA-registered laboratories

THANK YOU