

EDITORIAL

Regulations Overburden Health Care



BY CHRISTOPHER B. ZACHARY, M.D.

Any talk of health care reform must include a discussion of the money we're currently wasting on health care regulation. Recent data suggest that 47-60 million Americans are without

health insurance. Many people avoid seeking health care because it is too costly. If they do seek care, many become burdened by high costs.

According to an article from the Oct. 4, 2004 edition of Policy Analysis, a publication of the Cato Institute, the total cost of health care regulation exceeds \$339 billion, a figure that takes into account regulation of health care facilities, health

care professionals, health insurance, drugs and medical devices, the medical tort system, and the costs of defensive medicine. The article goes on to note that the benefit of health services regulation exceeds \$170 billion, leaving a net burden of health services regulation of \$169 billion.

I don't mind having health care regulations if they provide a benefit to society or more efficient practice. What I

can't stand is wasting money on health care regulations that serve no purpose. While we are being required to practice evidence-based medicine, we need to insist that the federal government practice evidence-based regulation.

In a 2002 report entitled "Care Without Coverage," the Institute of Medicine estimated that 18,000 uninsured Americans die every year because of a lack of health insurance coverage. According to the median estimate of four studies cited in the Policy Analysis article, an additional 22,000 people die every year due to reduced societal income related to health care regulations. So clearly, there is a human cost related to health care regulations that is unappreciated.

How can we reduce or eliminate excessive costs of regulation? We can start by devising a stripped down, simplified set of core regulations. We need to consider scrapping all regulations that have a negative cost/benefit ratio and regulations for which there is no evidence-based rationale. The emphasis cannot be simply on reducing costs; it needs to be based on factual evidence and improved quality of health care.

One way to achieve this is to overhaul the Food and Drug Administration, an agency that is overly restrictive, takes too long to make decisions, and is hamstrung with isolation, hesitation, and fear of bad results. Many aspects of drug safety could instead be certified and ensured by independent, private sector, voluntary institutions and by the tort system.

An overhauled FDA should provide a system of transparent peer review in the decision-making process regarding drugs and devices submitted.

Data submitted to the FDA for approvals by drug and device companies should be made immediately available upon clearance of any product. Those companies should also be required to provide serious, concise, and truthful postmarket reporting.

Our health care system is suffering because the current system is all about money, and not about people. ■

DR. ZACHARY is professor and chair of the department of dermatology at the University of California, Irvine.

For a video interview with Dr. Zachary, go to www.youtube.com/SkinAndAllergyNews.

LETTERS

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Refissa
Tretinoin Cream,
USP (Emollient) 0.05%

Refissa® [Tretinoin Cream, USP (Emollient) 0.05%]**Brief Summary of Full Prescribing Information****DESCRIPTION**

Tretinoin is available as Refissa® [Tretinoin Cream, USP (Emollient)] at a concentration of 0.05% w/w in a water-in-oil emulsion formulation consisting of light mineral oil, sorbitol solution, hydroxyoctacosanyl hydroxystearate; methoxy PEG-22/dodecyl glycol copolymer, PEG-45/dodecyl glycol copolymer, stearytrimethylsilane and stearyl alcohol, dimethicone 50 cs, methylparaben, edetate disodium, propylparaben, butylated hydroxytoluene, citric acid monohydrate, and purified water.

INDICATIONS AND USAGE

Refissa® is indicated as an adjunctive agent for use in the mitigation (palliation) of fine wrinkles, mottled hyperpigmentation, and tactile roughness of facial skin in patients who do not achieve such palliation using comprehensive skin care and sun avoidance programs alone. Neither the safety nor the effectiveness of Tretinoin Cream, USP (Emollient) for the prevention or treatment of actinic keratoses or skin neoplasms has been established. (Please see third bullet point in this section of the full prescribing information for additional populations in which effectiveness has not been established.) Refissa® DOES NOT ELIMINATE WRINKLES, REPAIR SUN DAMAGED SKIN, REVERSE PHOTO-AGING, or RESTORE A MORE YOUTHFUL or YOUNGER DERMAL HISTOLOGIC PATTERN.

Refissa® should only be used under medical supervision as an adjunct to a comprehensive skin care and sun avoidance program that includes the use of effective sunscreens (minimum SPF of 15) and protective clothing when desired results on fine wrinkles, mottled hyperpigmentation, and roughness of facial skin have not been achieved with a comprehensive skin care and sun avoidance program alone.

Neither the safety nor the efficacy of using TRETINOIN CREAM, USP (EMOLLIENT) daily for greater than 48 weeks has been established, and daily use beyond 48 weeks has not been systematically and histologically investigated in adequate and well-controlled trials.

CLINICAL TRIALS DATA

The Spear Refissa bioequivalence 6-month study of 382 patients revealed Refissa and Renova 0.05% products are bioequivalent.** In effect, Refissa and Renova 0.05% demonstrated no statistical difference from one another, neither product being superior to the other, but both proved superior to placebo.

Refissa Results:

	Improvement	No Improvement
Fine Facial Wrinkles	71%	29%
Mottled Hyperpigmentation	83%	17%

Fine facial wrinkles and hyperpigmentation were scored at baseline and at Week 24 by the investigator using a 10-point scale on which 0 represents no damage, 2-3=mild, 4-5=moderate, 6-7=moderate/severe and 8-9=severe. The change was calculated as baseline minus the Week 24 evaluations.*

**Please note: The clinical data in the package insert are from Ortho Pharmaceuticals original clinical trials for Renova 0.05% as required for FDA approval.

*Data on File, Spear Pharmaceuticals.

CONTRAINDICATIONS

This drug is contraindicated in individuals with a history of sensitivity reactions to any of its components. It should be discontinued if hypersensitivity to any of its ingredients is noted.

WARNINGS

TRETINOIN CREAM, USP (EMOLLIENT) is a dermal irritant, and the results of continued irritation of the skin for greater than 48 weeks in chronic, long term use are not known.

Safety and effectiveness of TRETINOIN CREAM, USP (EMOLLIENT) in individuals with moderately or heavily pigmented skin have not been established.

Refissa® [TRETINOIN CREAM, USP (EMOLLIENT)] should not be administered if the patient is also taking drugs known to be photosensitizers (e.g., thiazides, tetracyclines, fluoroquinolones, phenothiazines, sulfonamides) because of the possibility of augmented phototoxicity.

Because of heightened burning susceptibility, exposure to sunlight (including sunlamps) should be avoided or minimized during use of

Refissa®. Patients must be warned to use sunscreens (minimum of SPF of 15) and protective clothing when using Refissa®. Patients with sunburn should be advised not to use until fully recovered. Patients who may have considerable sun exposure due to their occupation and those patients with inherent sensitivity to sunlight should exercise particular caution when using and assure that the precautions outlined in the Patient Package Insert are observed.

Refissa® should be kept out of the eyes, mouth, angles of the nose, and mucous membranes. Topical use may cause severe local erythema, pruritus, burning, stinging, and peeling at the site of application. If the degree of local irritation warrants, patients should be directed to use less medication, decrease the frequency of application, discontinue use temporarily or discontinue use altogether.

Tretinoin has been reported to cause severe irritation on eczematous skin and should be used only with utmost caution in patients with this condition.

PRECAUTIONS

General: If a drug sensitivity, chemical irritation, or a systemic adverse reaction develops, use should be discontinued.

Drug Interactions: Concomitant topical medication, medicated or abrasive soaps, shampoos, cleansers, cosmetics with a strong drying effect, products with high concentration of alcohol, astringents, spices or lime, permanent wave solutions, electrolysis, hair depilatories or waxes, and products that may irritate the skin should be used with caution in patients being treated because they may increase irritation with use. Refissa® should not be administered if the patient is also taking drugs known to be photosensitizers (e.g., thiazides, tetracyclines, fluoroquinolones, phenothiazines, sulfonamides) because of the possibility of augmented phototoxicity.

Carcinogenesis, Mutagenesis, Impairment of Fertility

There was no evidence of carcinogenic potential when tretinoin was administered topically at a dose 5 times the average recommended human topical clinical dose. The mutagenic potential of tretinoin was evaluated in the Ames assay and in the in vivo mouse micronucleus assay, both of which were negative.

Pregnancy: Pregnancy Category C

There are no adequate and well-controlled studies in pregnant women. Refissa® should not be used during pregnancy.

Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, **caution should be exercised when administered to nursing women.**

Pediatric Use: Safety and effectiveness in patients less than 18 years of age have not been established.

Geriatric Use: Safety and effectiveness in individuals older than 50 years of age have not been established.

ADVERSE REACTIONS

(See WARNINGS and PRECAUTIONS sections.)

Local reactions such as peeling, dry skin, burning, stinging, erythema, and pruritus were reported by almost all subjects during therapy. These signs and symptoms were usually of mild to moderate severity and generally occurred early in therapy.

OVERDOSAGE

Application of larger amounts of medication than recommended has not been shown to lead to more rapid or better results, and marked redness, peeling, or discomfort may occur. Oral ingestion of the drug may lead to the same side effects as those associated with excessive oral intake of Vitamin A.

DOSAGE AND ADMINISTRATION

Refissa® [TRETINOIN CREAM, USP (EMOLLIENT)] should be applied to the face **once a day** before retiring using only enough to cover the entire affected area lightly. Patients should gently wash their face with a mild soap, pat the skin dry, and wait 20 to 30 minutes before applying. **The patient should apply a pea-sized amount of cream** to cover the entire face lightly. Special caution should be taken when applying the cream to avoid the eyes, ears, nostrils, and mouth. With discontinuation of therapy, a majority of patients will lose most mitigating effects on fine wrinkles, mottled hyperpigmentation, and tactile roughness of facial skin; **however, the safety and effectiveness of using TRETINOIN CREAM, USP (EMOLLIENT) daily for greater than 48 weeks have not been established.**

Manufactured by DPT Laboratories, San Antonio, TX 78215
Distributed by Spear Dermatology Products,
Randolph, NJ 07869

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