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via email to PCAC@fda.hhs.gov

Ms. Cindy Hong
Center for Drug Evaluation and Research
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 31, Rm. 2417
Silver Spring, MD 20993-0002

Subject: Pharmacy Compounding Advisory Committee
Regulation of Topical and Other Products
81 Fed. Reg. 69062 (Oct. 5, 2016)
FDA Docket No. 2016-N-0001

Gentlemen:

These comments are filed jointly on behalf of our clients, The Senior Citizens League and the Center for Medical Freedom.

The Senior Citizens League (“TSCL”) (www.tscl.org) is a nonprofit, non-partisan social welfare organization incorporated under the laws of Colorado, and is tax-exempt under Section 501(c)(4) of the Internal Revenue Code of 1986. TSCL, headquartered in Alexandria, Virginia, is known as one of the largest U.S. organizations engaging in education and advocacy on behalf of senior citizens. Its mission is to educate the public and alert senior citizens about their rights and freedoms as U.S. citizens, to assist members and supporters regarding those rights, and to protect and defend the benefits senior citizens have earned.

TSCL has nearly one million senior citizen members and supporters. Its activities include monitoring developments in the United States with respect to the interests of senior citizens and defending those interests before government, developing educational materials designed to explain to senior citizens their various rights as U.S. citizens, raising the level of public awareness of senior citizens’ rights by conducting surveys and polls, and publishing and distributing informational newsletters to members, supporters, and the public.

The Center for Medical Freedom (www.centerformedicalfreedom.org) is a project of the Conservative Legal Defense and Education Fund, which was founded three decades ago in 1985 as a nonprofit, non-partisan educational organization incorporated under the laws of

Virginia, and is tax-exempt under Section 501(c)(3) of the Internal Revenue Code. CMF's mission is to educate members of the public about their right to make their own personal medical and healthcare choices, and their inherent right of self-defense to resist efforts by government at all levels to restrict and control those choices.

FDA Proposal

The *Federal Register* Notice states that the Pharmacy Compounding Advisory Committee will be considering regulation of transdermal patches, creams, and five listed substances.

However, subsequent to the publication of the notice, certain members of the public were advised by the FDA that the topic of regulation of creams in compounding and the use of the five specific substances identified in the notice would be postponed until the next meeting of the Pharmacy Advisory Committee. That would leave for this time consideration of the regulation of only the use of patches at this meeting. If this is not correct, the entire matter should be re-noticed and deferred to a later time.

Initial Comment on Composition of Advisory Committee

It is our understanding that the Advisory Committee includes only one compounding pharmacist out of its 14 members, with the others being generalists in pharmacology. It would be our view that an Advisory Committee regulating compounding pharmacists should include a majority of members who are compounding pharmacists. These commenters have little confidence in recommendations made by an Advisory Committee which is not drawn from persons with the specific expertise and experience in the specific field involved, so that they can make informed judgments about compounding. It would be our view that the Advisory Committee as currently constituted should be extremely careful about restricting the access of compounding pharmacists to substances which they use to improve the lives of seniors and others. It is unrealistic to assume that members of such Advisory Committees do not carry with them inherent biases and preferences, and including only one compounding pharmacist on this Advisory Committee renders its recommendations highly suspect.

Comments

1. It is our understanding that compounding pharmacists rarely use patches in compounding, which are generally used for time release drugs. Therefore, this restriction would appear to have minimal effect. Nonetheless, in the absence of information indicating that serious problems have arisen from use of patches by compounding pharmacists, even this option should not be banned.

2. Creams are an entirely different matter. Should the possible regulation of creams still be on the table for this meeting, these commenters urge that there be no new restrictions imposed on their use by compounding pharmacists.

Such creams are used, for example, to create products such as antiperspirants for persons with extremely sensitive skin who react badly to commercially available products. They are used to develop products designed to treat a number of dermatological conditions. In both cases, seniors are particularly likely to benefit from access to such compounded products.

Additionally, creams are often used by compounding pharmacists to provide effect pain treatments for returning, injured and recovering Veterans, frequently combining various pharmaceuticals for maximum benefit. Barring access to such pain compounded creams would be unconscionable.

Lastly, creams are essential to the production and application of bio-identical hormones, which are much better for many persons than commercially available substitutes. Any policy which is designed to limit use of creams by compounding pharmacists for this purpose would be viewed by the nation's senior citizens as an arrow aimed at their access to necessary and reasonably priced pharmaceuticals.

3. If the five substances identified in the *Federal Register* notice are still on the table for consideration at this meeting, then it is recommended that the Committee take no steps to ban their use by compounding pharmacists.

Glycolic Acid, for example, is used in a wide variety of skin care products. It has many beneficial effects when applied to the skin, and treats a variety of skin conditions. It makes no sense to ban access to Glycolic Acid to compounding pharmacists when that same substance is widely used in manufactured products. There must be some fairness built into the FDA regulations, and if a substance can be used by large companies manufacturing over-the-counter skin care products, it certainly should be able to be used by compounding pharmacists.

4. It has become clear from a number of FDA proceedings that the FDA is completely insensitive to the real financial constraints that exist with respect to tens of millions of Americans — a large number of which are seniors.

In a recent proceeding involving a Draft Guidance on Compounded Drug Products that are essentially copies of a commercially available product, FDA-2016-1309, the FDA took the position that “lower price is not sufficient to establish that the compounded drug product is not essentially a copy of the commercially available product.” This is the type of argument that would appeal only to a well-paid bureaucrat. In the real world, Americans have been confronted with sharp increases in the price of many pharmaceuticals which they need. The FDA appears wholly insensitive to the fact that higher price often means that seniors and others on limited budgets often will do without. In other cases, more dangerous substitutes

may be chosen. It is time for the FDA to stop working against the interests of the American people, and to give high consideration to cost — rather than treating it as an irrelevancy.

5. Lastly, having observed many FDA proceedings and participated in some, these commenters have come to the conclusion that the trend at the FDA is to prefer products manufactured by large pharmaceutical companies over those prepared by compounding pharmacies, and that if the trend continues, eventually compounding pharmacies will be robbed of the substances that they need to provide low cost and tailored alternatives to the products of Big Pharma. This is an unacceptable trend, and should be stopped and eventually reversed.

Conclusion

If any topics other than patches are on the agenda for this meeting, those other topics should be tabled to the next meeting, and the public given a reasonable opportunity to provide comments.

Sincerely yours,

/s/

William J. Olson

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