Committee’s Primary Research Conclusions

• Data are inadequate to conclusively support conclusions regarding safety and risks related to the use of any compounded topical pain creams.

• High levels of systemic absorption of certain APIs in topical pain creams have occurred, potentially enabled by excipient selection.

• A substantial amount of high-quality research is still needed to identify effectiveness in all APIs reviewed as well as the relative risk for adverse effects in response to absorption of compounded topical pain creams.
Three additional critical areas of concern related to safety and effectiveness of compounded topical pain creams should be addressed:

1. Inadequate federal and state level regulation and oversight
2. Lack of data collection and surveillance
3. Inadequate level of training and education for health care providers and individuals who compound
Committee’s Overarching Conclusions

- There is limited evidence to support the use of compounded topical pain creams to treat pain conditions in the general adult population. The few APIs that show potential effectiveness in compounded topical pain creams (i.e., doxepin, naproxen, lidocaine) are already available in FDA-approved topical products used to treat pain.

- In context of the recent rise in supply and demand of compounded preparations, lack of evidence regarding systemic absorption of ingredients used in compounded topical pain creams gives rise to a substantial public health concern. It is important to consider the potential effects and safety of all compounds (including APIs and excipients) that may permeate the skin.
There is an opportunity for the U.S. Department of Health and Human Services to provide additional oversight to ensure the safety of compounded pain creams, with prioritized focus on those containing APIs that, when applied topically, cross the skin barrier to enter the bloodstream and act systemically within the body.
To prescribing clinicians, compounding pharmacists, and other health professionals who compound topical pain cream preparations:

Caution should be used when prescribing or dispensing compounded topical pain cream preparations.
Recommendation 2

To pain researchers, public and private funding agencies, and relevant patient advocacy organizations:

Strengthen and expand the evidence base on the safety and effectiveness of APIs and excipients commonly used in compounded topical pain creams.
Recommendation 2

To pain researchers, public and private funding agencies, and relevant patient advocacy organizations:

Strengthen and expand the evidence base on the safety and effectiveness of APIs and excipients commonly used in compounded topical pain creams.
Recommendation 3

To state boards of pharmacy, schools of pharmacy, and nonprofit professional societies and organizations within the medical and pharmaceutical sectors:

Require continued training for clinicians who prescribe compounded pain medication, particularly pain management specialists.

Revise current educational requirements for compounding pharmacists and non-pharmacists who compound.
Recommendation 4

To National Association of Boards of Pharmacy:

Additional state-level oversight of compounded topical pain creams is needed to improve safety and effectiveness.
Recommendation 4

To FDA and global standards-setting organizations (e.g., U.S. Pharmacopeia):

Develop standard processes for testing APIs (in solitute and combinations) and excipients commonly used in compounded topical pain creams.
Final Thoughts

- In absence of well-designed, high-quality studies on the efficacy of APIs in compounded topical pain creams, there is a public health concern for potential harms.
- Current data on safety and risks are inadequate.
- Compounded topical pain creams should be prescribed and dispensed with utmost caution.