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Testimony Before the Food and Drug Administration's Pharmacy Compounding Advisory Committee Regarding Placing MOTS-c on the 503A Bulks List: No Human Studies or Proven Benefits, But Possible Risks

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Thank you for the opportunity to testify today. I am Azza AbuDagga, a Health Services Researcher at Public Citizen, a national public interest organization. Public Citizen and I have no financial conflicts of interest.

We strongly oppose placing MOTS-c-related bulk drug substances[1] — in either the native molecule (free base, naturally occurring) or acetate (synthetic) form — on the 503A Bulks List[2] because the hype around them is not backed by science.

We share the concerns of the Food and Drug Administration (FDA) scientists that the available MOTS-c products are not well characterized from the physical and chemical standpoints.[3] This means that the exact naming conventions, makeup, and purity of these products do not meet regulatory and scientific standards.

Moreover, there are *no* published human studies for MOTS-c. We found a single small phase 1 human study examining the effect of an experimental modified MOTS-c analog, called CB4211, on liver injury biomarkers in only 11 subjects who received daily injection of the drug for four weeks,[4] but the drug's clinical development was discontinued.

As discussed by the FDA scientists, the only available evidence for MOTS-c is confined to small non-clinical pharmacological studies spanning a few weeks. These studies are limited to rodent models and cell cultures that evaluated the effect of MOTS-c products on biological processes that "could be relevant to the nominated uses," including

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[1] MOTS-C stands for mitochondrial open reading frame of the 12S rRNA-c. It is a 16-amino-acid peptide.
[2] The 503A Bulk List includes bulk drug substances that can be used to compound drug products in accordance with section 503A of the Federal Food, Drug, and Cosmetic Act.
[3] Food and Drug Administration. FDA briefing document for MOTS-c-related bulk drug substances (MOTS-c (free base) and MOTS-c acetate) prepared for the July 23-24, 2026, meeting of the Pharmacy Compounding Advisory Committee. May 11, 2026. https://www.fda.gov/media/193347/download. Accessed July 21, 2026.
[4] Loomba R, Hompesch M, Salazar S, et al. CB4211, a Novel analog of MOTS-c, improves markers of liver injury and metabolism in obese subjects with nonalcoholic fatty liver disease: A multicenter, double-blind, randomized, placebo-*controlled study. Hepatology.* 2021;74(6):1395A.

managing obesity or osteoporosis. However, we cannot base human use on these studies. Also, no studies examined dose-response relationships for MOTS-c effects.

Other concerns include the lack of evidence regarding potential impurities and aggregation of MOTS-c products, as well as their potential risk of triggering unwanted immune reactions.

MOTS-c does not target cell-surface receptors; rather, it enters the nucleus. Therefore, exogenous MOTS-c can potentially alter DNA expressions in ways that we do not understand. This possibly can make the long-term risks of these products outweigh any possible short-term benefits.

Increasing the availability of MOTS-c by easing restrictions on its compounding at this time would be premature.

If MOTS-c were included in the 503A Bulks List, it would represent a significant step backwards. This would create a dangerous precedent that would certainly be used to pressure the FDA to permit the compounding of other unproven, potentially risky products.

Therefore, we urge the committee to vote against placing MOTS-c on the 503A Bulks List.