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Testimony Before the Food and Drug Administration’s Pharmacy Compounding Advisory Committee About BPC-157 (Free Base) and BPC-157 (Acetate)

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I am Nina Zeldes, a Health Researcher at Public Citizen’s Health Research Group. We have no financial or other conflicts of interest.

Public Citizen strongly supports the assessment of the Food and Drug Administration (FDA) that BPC-157 should not be included in the 503A Bulks List.¹

Many peptides have the potential to be turned into safe and effective drugs; some of these drugs are approved by the FDA and others are in clinical trials.² This is not the case for BPC-157. The substance’s supposed benefits are largely based on anecdotal evidence, and the interest in it appears to be driven by those who stand to benefit from increased demand.³

¹ Food and Drug Administration. FDA briefing document for BPC-157 – related bulk drug substances (BPC-157 (free base) and BPC-157 acetate) prepared for the July 23-24, 2026, meeting of the Pharmacy Compounding Advisory Committee. May 11, 2026. <https://www.fda.gov/media/193343/download>. Accessed July 23, 2026.

² Willyard C. Is the peptide craze backed by science? The promise behind the hype. *Nature*. 2026;654(8118):312-314.

³ Peter Whoriskey. The “miracle drug” and the peptide craze breaking the FDA. Public Citizen. June 16, 2026. <https://www.citizen.org/article/the-miracle-drug-and-the-peptide-craze-breaking-the-fda/>. Accessed July 26, 2026.

Although BPC-157 was discovered in the early 1990s, there are still no adequate data about its safety or effectiveness.⁴ Clinical trials have been limited in scope. Some trials have not been published or otherwise made public.^{5,6,7}

In 2023 the FDA added 19 peptides, including BPC-157, to a do not compound list, because of insufficient data about harms.^{8,9} Since then, no new clinical evidence has become available to demonstrate that BPC-157 is either effective or safe.¹⁰

For ulcerative colitis, the FDA identified only one randomized, placebo-controlled trial that evaluated BPC-157.¹¹ This trial was completed by only 46 participants, who received the peptide as an enema or received a placebo once daily. Not only was this trial small, but it lasted only two weeks. Moreover, because (according to the FDA) the results were only reported in a meeting abstract, important details such as the primary endpoint, the inclusion or exclusion criteria, and the statistical design are not known. There are no clinical data supporting the peptide's use via the proposed routes of administration, such as oral, rectal suppositories, subcutaneous, nasal, or transdermal.

⁴ Food and Drug Administration. FDA briefing document for BPC-157 – related bulk drug substances (BPC-157 (free base) and BPC-157 acetate) prepared for the July 23-24, 2026, meeting of the Pharmacy Compounding Advisory Committee. May 11, 2026. <https://www.fda.gov/media/193343/download>. Accessed July 23, 2026.

⁵ Talpos S. How a Croatian lab spawned a buzzy peptide now popular with MAHA. *Undark*. February 3, 2026. <https://undark.org/2026/02/03/bpc-157-peptide-fda/>. Accessed July 23, 2026.

⁶ Khullar D. Why are people injecting themselves with peptides? Health and wellness influencers are hawking unapproved treatments on the gray market. The future of the F.D.A.—and the health of consumers—is at stake. *The New Yorker*. April 6, 2026. <https://www.newyorker.com/magazine/2026/04/13/why-are-people-injecting-themselves-with-peptides>. Accessed July 23, 2026.

⁷ Talpos S. The hidden history of BPC-157, a favorite MAHA peptide. *Stat News*. June 1, 2026. <https://www.statnews.com/2026/06/01/bpc-157-researcher-predrag-sikiric-addresses-skeptics-questions/>. Accessed July 23, 2026.

⁸ Food and Drug Administration. Certain bulk drug substances for use in compounding that may present significant safety risks. September 27, 2024. <https://web.archive.org/web/20241112124122/https://www.fda.gov/drugs/human-drug-compounding/certain-bulk-drug-substances-use-compounding-may-present-significant-safety-risks>. Accessed July 23, 2026.

⁹ Khullar D. Why are people injecting themselves with peptides? Health and wellness influencers are hawking unapproved treatments on the gray market. The future of the F.D.A.—and the health of consumers—is at stake. *The New Yorker*. April 6, 2026. <https://www.newyorker.com/magazine/2026/04/13/why-are-people-injecting-themselves-with-peptides>. Accessed July 23, 2026.

¹⁰ Knoepfler P. Did Kennedy just stack the deck on FDA oversight of peptides? *STAT News*. April 29, 2026. <https://www.statnews.com/2026/04/29/rfk-jr-peptides-upcoming-fda-policy-shift-compounding-drugs/>. Accessed July 23, 2026.

¹¹ Food and Drug Administration. FDA briefing document for BPC-157 – related bulk drug substances (BPC-157 (free base) and BPC-157 acetate) prepared for the July 23-24, 2026, meeting of the Pharmacy Compounding Advisory Committee. May 11, 2026. <https://www.fda.gov/media/193343/download>. Accessed July 23, 2026.

The FDA could not identify any clinical trials assessing the efficacy of BPC-157 for Crohn's disease, Celiac disease, or tendonitis.

The agency evaluated 25 non-clinical studies. We agree with the FDA that the results of non-clinical studies should be "interpreted with caution."¹² Importantly, no dedicated receptor in the body for BPC-157 has been identified, a dose-response relationship has not been established, and the purported mechanism of action is unknown.

The FDA identified only five clinical studies that assessed the safety of BPC-157. All were likely only exploratory, and none included the proposed oral, subcutaneous, nasal, or transdermal routes.¹³ Although no serious adverse events were reported, all five studies were small (including between two and 26 participants) and very short. Some studies covered only a single procedure, and none lasted longer than two weeks.

There are additional concerns about BPC-157.¹⁴ Impurities and changes in chemical composition that may be triggered by the manufacturing process or storage conditions can increase the risk of immune responses, particularly when the substance is injected.¹⁵ Moreover, naming conventions are inconsistent and BPC-157 is not well characterized. "BPC-157" can refer to inconsistent formulations for each of the free base and the acetate with potentially unique safety and efficacy profiles.

Finally, Public Citizen is very concerned about the conflicts of interest of several members of this committee regarding peptides.

BPC-157 should go through the standard FDA approval process for new drugs and not be added to the 503A Bulks List.¹⁶ Adding BPC-157 to the 503A Bulks List would set a dangerous regulatory precedent and put patients at risk. We therefore urge the committee to vote against placing this peptide on this list.

¹² *Ibid.*

¹³ *Ibid.*

¹⁴ *Ibid.*

¹⁵ Damon A. RFK Jr. May reverse a peptide ban he calls "Illegal." Former FDA officials say he mischaracterized their work. *ProPublica*. April 3, 2026. <https://www.propublica.org/article/peptide-safety-fda-compounding-pharmacies>. Accessed July 23, 2026.

¹⁶ Public Citizen. Easing restrictions on peptides: Will the FDA stand for science or toady up to RFK Jr.? April 15, 2026. <https://www.citizen.org/news/easing-restrictions-on-peptides-will-the-fda-stand-for-science-or-toady-up-to-rfk-jr/>. Accessed July 23, 2026.