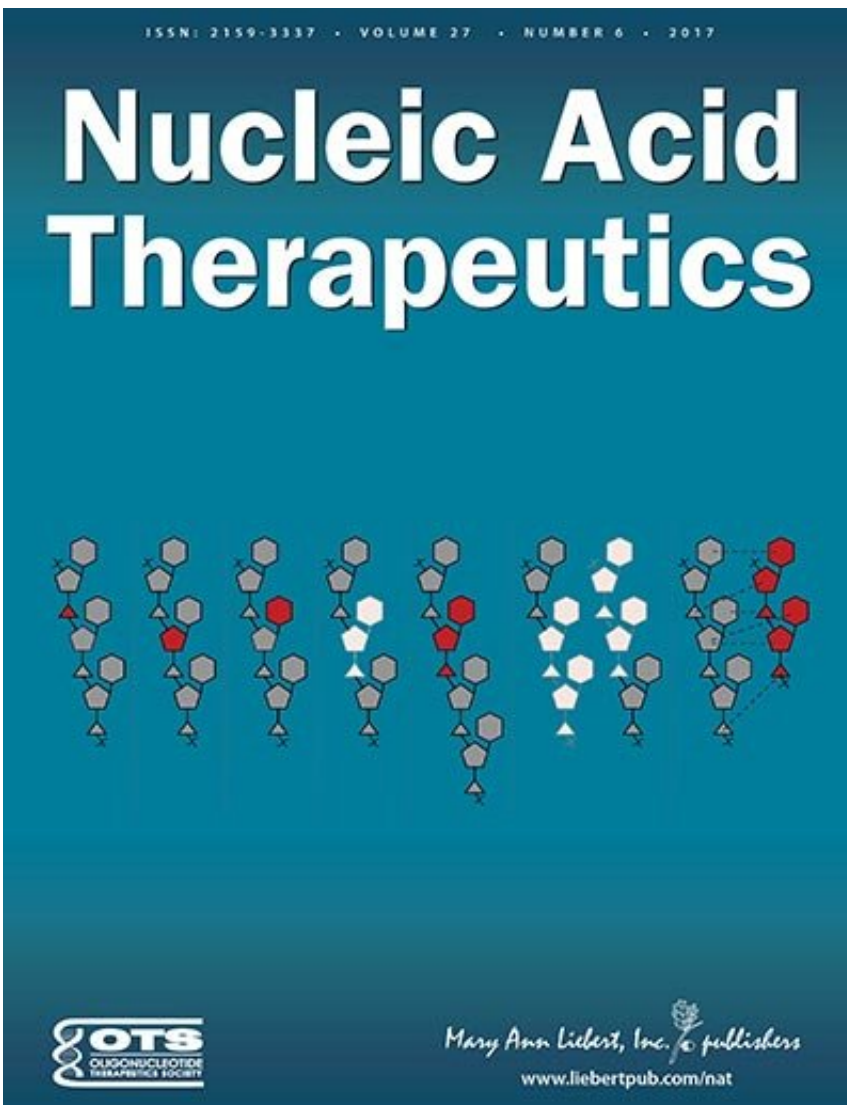


# Oligonucleotide drug producers coauthor report on drug impurities

December 12 2017

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Credit: Mary Ann Liebert, Inc., publishers

A new addition to a series of articles that focus on important topics related to the development of oligonucleotide therapeutics presents an in-depth look at the identification, characterization, and reporting of product-related impurities. The article entitled "Impurities in Oligonucleotide Drug Substances and Drug Products," which covers both the chemistry and safety aspects of impurities and provides scientific advice on impurity qualification requirements, is published in *Nucleic Acid Therapeutics*.

Daniel Capaldi, Ionis Pharmaceuticals, and coauthors from AstraZeneca, ProQR Therapeutics, Alnylam Pharmaceuticals, Anavex Life Sciences, GlaxoSmithKline, ISA Therapeutics, and Celgene catalogued the [oligonucleotide](#) impurities reported in the scientific literature and broadly grouped them based on structure. Based on their experience, they have found that efforts to characterize impurities in these substances often lead to process improvements in [drug](#) synthesis and ultimately higher purity drug products. Furthermore, the similarities among oligonucleotide therapeutics and their methods of synthesis increase the likelihood that information gained from studying one drug substance can be applied to another.

"For advances to happen, regulatory agencies, funding sources, and therapeutic oligonucleotide developers alike need to be able to understand the progress, and the remaining concerns. The clarity and candor of this much-needed multi-stakeholder white paper on the impurities associated with oligonucleotide therapeutic production adds a vital discussion to our ongoing series of white papers," says Executive Editor Graham C. Parker, PhD, The Carman and Ann Adams Department of Pediatrics, Wayne State University School of Medicine, Children's Hospital of Michigan, Detroit, MI.

**More information:** Daniel Capaldi et al, Impurities in Oligonucleotide Drug Substances and Drug Products, *Nucleic Acid Therapeutics* (2017).

[DOI: 10.1089/nat.2017.0691](https://doi.org/10.1089/nat.2017.0691)

Provided by Mary Ann Liebert, Inc

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