



Academy of
Managed Care
Pharmacy®

May 1, 2014

Ms. Jayne Peterson
Center for Drug Evaluation and Research
Food and Drug Administration
10903 New Hampshire Avenue
Building 31, Room 2417
Silver Spring, MD 20993

Re: Nomination of *Michael James Tocco, R.Ph., M.Ed.*, for Nonvoting Member of the Pharmacy Compounding Advisory Committee [Docket No. FDA-2013-N-0001]

Dear Ms. Peterson:

I am writing today on behalf of the Academy of Managed Care Pharmacy (AMCP) to proudly nominate Michael James Tocco, R.Ph, M.Ed. to serve as a nonvoting member of the Pharmacy Compounding Advisory Committee for the Food and Drug Administration. Michael is a pharmacist who has nearly 40 years of broad experiences in pharmacy, including serving as the current President of Premier Value Pharmacy Compounding Network and formerly as President of the Massachusetts Board of Pharmacy. Michael's direct involvement in developing the Premier Value Compounding Network, LLC (PVPCN) makes him uniquely qualified for this position. Specifically designed by its pharmacy and pharmacist members, PVPCN is an ethical and professional pharmacy network focused on the provision of quality compounded prescriptions at a fair and appropriate cost. In addition to his current direct role in compounding, Michael's role in pharmacy ownership, management, oversight, auditing and contracting, as well as his health plan and pharmacy benefit management experience will allow him to provide informed and current advice to the FDA and the Advisory Committee members on compounding issues.

Michael has personally told me that, if necessary, he would resign from his position as President of PVPCN to serve as member of this Advisory Committee. This, along with both his long-tenured dedication to pharmacy practice and pharmacists and his volunteer work with AMCP and other similar organizations also serve to demonstrate his integrity and commitment to service.

AMCP is a national professional association of pharmacists, physicians, nurses, and other health care practitioners who serve society by the application of sound medication management principles and strategies to achieve positive patient outcomes. The Academy's nearly 7,000 members develop and provide a diversified range of clinical, educational and business management services and strategies on behalf of the more than 200 million Americans covered by managed care pharmacy benefits.

Michael's work to ensure ethical oversight and professional standards for compounded products began approximately two years ago. Several pharmacy owners and managers approached Michael to develop a compounding network that would provide compounded products according to standards that exceed those

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of the United States Pharmacopeia (USP) Chapter 795 standards for non-sterile preparations. Currently, members of the PVPCN compound only 795 patient specific medications, based on the standards for efficacy and safety established by the members. Currently, members of PVPCN do not compound sterile products because it has determined that the patients served benefit most from receiving high-quality, non-sterile products at an appropriate price. Examples of standards that PVPCN members must meet include:

- Reviews of the compounding area by microbiologists in conjunction with the onsite pharmacy inspection team
- Surface, air, and product testing by outside certified labs
- Submission of self-surveys with copies sent in with validation of continued testing results

In addition, Michael has been involved in clean room design, construction, and licensing – and more recently, the development of quality standards for networks that exceed the USP 795 standards. He is also developing a Quality Survey Process for Compounding Community Pharmacies for Integrated Pharmacy Solutions, a pharmacy management consulting company where he serves as the Founder and Chief Executive Officer. I have taken the liberty of attaching Michael’s curriculum vitae, which provides more detailed information about his distinguished career as a pharmacist.

AMCP again thanks the FDA for the opportunity to nominate Michael Tocco for the Advisory Committee. I am confident that the public would be well served by his appointment, as Michael will work tirelessly to ensure the highest standards for compounded products in the United States. If I can answer any questions or provide additional information, please contact me at (703) 683-8416 or erosato@amcp.org.

Sincerely,



Edith A. Rosato, R.Ph., IOM
Chief Executive Officer

Cc: The Honorable Senator Edward Markey

Attachment: CV for Michael James Tocco, R.Ph., M.Ed.