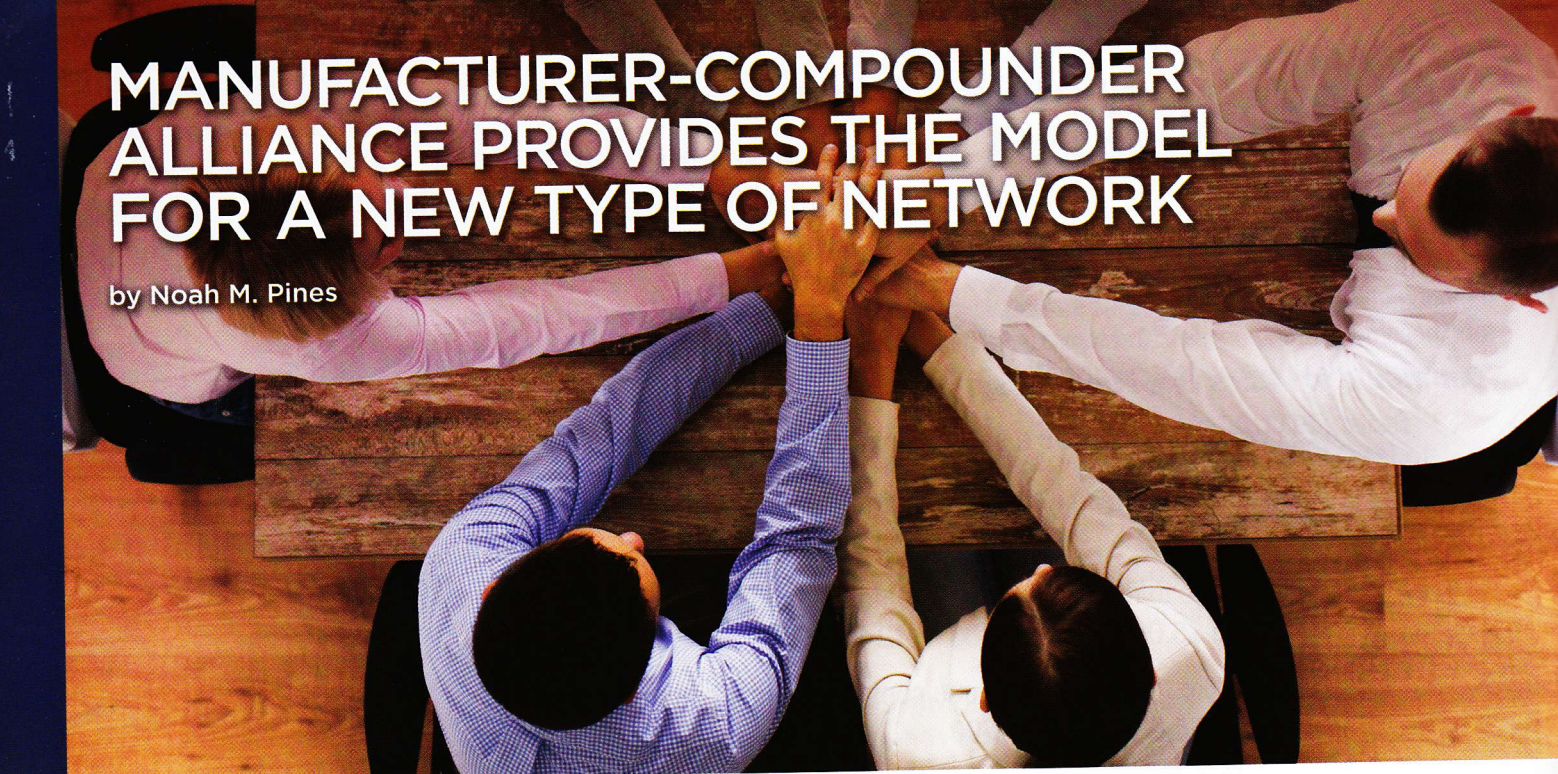


OLD DOGS

OLD TRICKS





MANUFACTURER-COMPOUNDER ALLIANCE PROVIDES THE MODEL FOR A NEW TYPE OF NETWORK

by Noah M. Pines

Johnson Compounding & Wellness in Waltham, Mass. looks like many other compounding pharmacies. It has large, bright, sterile and non-sterile compounding labs, a call center for handling prescriptions, and a broad range of homeopathic medications and supplements to meet the needs of patients.

However, Johnson Compounding & Wellness has one thing that is different from many other compounding pharmacies: it has a direct contract with Lumara Health (a division of AMAG Pharmaceuticals) to dispense FDA-approved Makena® (hydroxyprogesterone caproate injection). Like many compounders, Johnson's used to compound a version of this drug, commonly known as "17P."

So in addition to preparing many compounded medications, Johnson Compounding & Wellness operates, in essence, as a specialty pharmacy for patients prescribed Makena.

"Strong relationships with physicians' offices and a major focus on customer service made Johnson's a perfect candidate for such a partnership," said John Walczyk, PharmD, Pharmacy Manager. "Since Makena is commercially available and hasn't been in a shortage situation, pharmacists shouldn't compound it. We can get it quickly, keep it in stock, and we are successfully submitting claims for it. Additionally, Lumara helps patients who can't afford the therapy and there have been several patients of ours we've helped access their prescription assistance program."

Just a short while ago, a partnership between any compounding pharmacy and the makers of Makena would have seemed improbable, if not impossible.

When Makena was launched in 2011, its high initial price triggered a public outcry that led the US Food and Drug Administration (FDA) to exercise "enforcement discretion," an unprecedented step that allowed

pharmacists to continue to compound 17P. This move was applauded at first by multiple professional societies, including the American College of Obstetricians and Gynecologists (ACOG).

Typically, if a medication is FDA-approved and commercially available, compounding is limited to cases where the manufacturer's product can't meet the need for a particular patient (e.g., a different dose or formulation). FDA reversed its March 2011 position on Makena in June 2012, and returned to the customary FDA stance on the compounding of commercially available FDA-approved drugs, which restricts compounding of 17P to only those individual patients unable to take the approved drug.

The longstanding relationship between pharmacists and the medical community regarding 17P led to Lumara seeking out partnerships with these pharmacists. Lumara has created a network of geographically dispersed compounding pharmacies that now dispense Makena. Lumara worked with Massachusetts-based Gates Healthcare Associates, a consultancy that has pioneered clinical and entrepreneurial advances in the field of pharmacy compounding, headed by Ernest P. Gates, Jr., RPh. A longstanding leader in the field and an expert on the regulation and accreditation of compounding pharmacies, Gates is seen as one of the people who helped lead compounding pharmacy back to a prominent place in the healthcare ecosystem. Gates also invented the lozenge mold, which is used by compounding pharmacies in daily practice across the nation.

Gates and Senior Associate Bill Mixon, RPh, worked with compounding pharmacies to help them see the benefits of a potential partnership.

"In the past, the traditional model was to push the compounder aside," observed Mixon. "This is the first time I know of where a manufacturer has partnered with

compounding pharmacies. It is forward-thinking and we have proven that this model works – and we have high expectations for there to be other drugs distributed in this manner because it just makes sense.”

More than 50 pharmacies from across the nation are now in the Makena distribution network. Juxtaposed from Johnson Compounding & Wellness on the East Coast is A&O Pharmacy in Salinas, California, headed by Dave Smith, PharmD.

Smith read about John Walczyk’s experiences in an IACP blog post and decided to follow suit. Since both pharmacies had the ability to submit claims and both were PCAB-accredited, the credentialing process was straightforward.

The relationship with Lumara is not something that either Walczyk or Smith would have entertained four years ago when Makena was introduced. Both were passionate and protective about dispensing 17P given the need the drug addresses and their commitment to support physician practices.

“17P was rewarding to compound because you were addressing an important therapeutic area with no FDA-approved drug,” said Smith. “But the FDA told us to stop making it given the commercial availability. Now, we have a mutually beneficial relationship to dispense Makena.”

In addition to partnering with compounders, Lumara made other efforts to make the drug accessible and

affordable, including offering discounts to payers and a strengthened financial assistance program for patients.

According to Gates, for the pharmacies that formerly compounded 17P that are now dispensing Makena, their favorable experiences with this unlikely manufacturer-compounder alliance may be the harbinger of an entirely new business model, one where compounders dispense FDA-approved specialty injectable drugs.

“In health care today, practitioners and providers must evolve and adapt, or risk getting run over by broad systemic changes,” said Gates. “The new collaboration that we have created provides a model for compounding pharmacies to not only survive, but to thrive, in a dramatically changing healthcare environment.”

IACP Members who are interested in dispensing Makena should contact:

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