ISSUE BRIEF:

Compounding MOU: FDA has underestimated the administrative burden on states

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When Congress added section 503A to the Food, Drug & Cosmetic Act in 1997, it directed the FDA to come to an agreement with the states — a memorandum of understanding — to help FDA "address … the distribution of inordinate amounts of compounded drug products interstate."

The legislation offered the states a choice: They could sign the MOU and report to FDA on inordinate amounts of compounded medications shipped by in-state compounding pharmacies to patients in other states. Or don't sign it, and pharmacies in that state would be limited to shipping out-of-state no more than five percent of all prescription orders, even those that are patient-specific.

Congress' expectation, communicated in committee testimony and in Appropriations Committee reports to FDA, was that FDA would structure the MOU in such a way that states would be motivated to sign it. That motivation was to be an administrative regime that was workable for state boards of pharmacy, the agencies that in most states are charged with regulating pharmacy compounding and whose funding comes not from the federal government but from the state legislature. In return, states would collect and report data on in-state pharmacies that shipped more than 50 percent of their compounded drugs out of state.

If the MOU was to be the carrot, the cap on out-of-state shipments was the stick. Impeding patients' access to compounded meds was not Congress' goal. The goal was to incentivize states to help FDA gather data on large shippers of compounded drugs – so that it could properly inspect and document patient safety in those pharmacies.

For patients served by compounding pharmacies based in states that don't sign the MOU (many of whose lives are sustained by the compounded medications that are shipped to them) the loss of access to those drugs – because of that five percent cap on shipments – would be significant. There will also be an economic cost to states, as compounding pharmacies limited by the five percent cap close or relocate to a state that did sign the MOU.

FDA has had 23 years to create that MOU and get buy-in from the states. Unfortunately, the "final" MOU, released by FDA in May, fails to address earlier concerns raised by states and pharmacy groups. Now several states are hinting that they won't sign it. Rather than an enticing carrot, they see this final MOU itself as a stick, just another expensive unfunded mandate.

We believe FDA failed to account for the real costs of the regulation, and thus has violated the federal Paperwork Reduction Act. FDA conducted no survey of state boards of pharmacy but relied instead on old input provided to NABP on an earlier iteration of the MOU, a version that was later withdrawn. As a result – made clear by the number of states now threatening not to sign – FDA has underestimated the administrative cost to states that signing the MOU would incur and has over-estimated the number of states that will likely sign it.

As the final step in the process, the MOU has been submitted by FDA to the Office of Management and Budget for clearance under the Paperwork Reduction Act, which requires federal agencies to estimate the burden of federal regulations on state agencies.

ACTION REQUESTED: FDA has created a lose-lose proposition for states, not at all what Congress intended. Urge your Member of Congress to contact OMB *immediately* and ask them to send the MOU back to FDA to do a true collection of information on the MOU's burden on states, and then to present an MOU that states will a sign.

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