

**House Committee on Energy and Commerce, Subcommittee on Health, hearing:  
“Reforming the Drug Compounding Regulatory Framework”  
Questions for the Record from the Honorable John D. Dingell  
Response from The Pew Charitable Trusts**

**1. Do you believe that it is important to have clear lines of division between FDA and State boards of pharmacy when it comes to regulating compounding pharmacies? Please elaborate.**

To ensure effective regulatory oversight and provide clarity for compounders, it is important to establish which activities are subject to federal regulation. Current law provides neither clarity, nor an effective mechanism for regulation of large-scale compounders whose operations fall far beyond traditional pharmacy practice. Large-scale compounding cannot be addressed simply by asserting these facilities are making unapproved new drugs and requiring them to submit to the New Drug Approval or Abbreviated New Drug Approval process. For example, some large compounders have become a source of intravenous and epidural therapies for hospitals and health systems that do not have the capacity to compound them in-house. Large-scale compounding in anticipation of, or without a prescription is better suited to FDA oversight than to state oversight under current quality standards. However, FDA oversight of compounding need not preclude a facility from maintaining a pharmacy license and carrying out other state-regulated pharmacy practice activities.

**2. Does Section 503(a), as currently drafted and interpreted, recognize the existence of these compounding outsourcers and our reliance on them? Please elaborate.**

Current Section 503A does not address the existence of compounding “outsourcers”. Modern compounding includes a range of practices, such as preparation of individual doses, small batch compounding of sterile products, and larger batch sterile admixture for hospitals. Under current law, FDA may take action against a compounding facility that is creating unapproved new drugs, but has no ability to conduct routine inspections or enforce quality standards at outsourcers. Congress should update the current regulatory scheme to ensure the appropriate oversight structures and quality standards are in place.

**3. Do you believe that simply reinstating Section 503(a) would result in sufficient clarity regarding FDA's authority over compounding pharmacies? Please elaborate.**

Varying court rulings have created uncertainty about the status of section 503A. However, merely reinstating section 503A would leave a lack of clarity about which facilities were subject to FDA oversight, and would provide the agency with no way to prospectively identify compounders subject to its jurisdiction, exercise oversight or enforce quality standards. Reinstating 503A would have the practical effect of largely limiting FDA to taking action against compounders only after an adulterated and potentially dangerous drug has been produced and distributed. Congress should explicitly give FDA the tools and authority to hold these facilities to meaningful quality standards in order to prevent drugs from reaching patients.