VIEWPOINTS

Compounding Paradox: Taught Less and Practiced More

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Opposing Trends

Compounding dominated pharmacy's many thousands of years of history until post-World War II industrial pharmaceuticals surpassed it in the United States. During the 1960s, compounding in outpatient practice and pharmacy curricula began declining while hospital intravenous compounding was inconspicuously growing, ie, inpatient medication orders are ignored in most national prescription drug frequency surveys. Citing evidence in 1979 of some deficient compounding, Michael Stolar urged, "Colleges of pharmacy should ensure that their graduates have adequate compounding knowledge and skills."¹

The past 40 years of decreasing academic instruction in compounding is generally explained with the following "Compounding is" statements:

• superfluous with a plethora of manufactured dosage forms;
• menial compared to patient drug therapy management;
• too expensive to teach in terms of both faculty time and expendable materials;
• an insignificant percentage of outpatient pharmacy practice;
• not teachable, because of a shortage of qualified teachers.

In 2002, the US Food and Drug Administration (FDA) investigators estimated 250 million prescriptions were compounded, but did not delineate whether those were for outpatients only or outpatients plus inpatients. They also reported that 34% of 29 samples of compounded medications from 12 internet pharmacies failed a test for sterility or drug strength.² The author knows a pharmacist whose cancer research medical center compounded 1.5 million drug doses in 2001.

Total parenteral nutrition (TPN) circa 1970, has to be compounded shortly before administration, because amino acids and dextrose rapidly form non-nutritive products (Maillard reaction), and "one size does not fit all" patients' complex requirements. When the FDA issued a warning in 1994 advising the correct measuring sequence of TPN admixtures after 2 fatalities from precipitated calcium phosphate,³ there was implication for pharmacy curricula. Yet, PharmD students today are more likely being taught nutritional assessment theory than correct mixing practices of TPN in required courses.

Cause and Effect, or Coincidence?

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A resurgence of community compounding in the 1980s included opening of the Professional Compounding Centers of America (PCCA) (www.pceutics.com) that markets training, bulk drugs, equipment, and on-line pharmaceutics courses. Recently, PCCA president, David Sparks, stated, "The place to start [compounding] is with the proper education."⁴ The 1980s also saw growth of compounding supply businesses, such as Gallipot (St. Paul, MN), Paddock Laboratories, Inc. (Minneapolis, MN), and Spectrum Pharmacy Products (New Brunswick, NJ). During the 1990s, PCCA staff pharmacists began visiting pharmacy schools to promote patient benefits and professional rewards of compounding to students.

Since 1990, approximately 10 widely publicized compounding errors injured or killed patients, most because of bacterial contamination. Information is lacking to compare the quality of academic instruction of the involved pharmacists with the gravity of their errors. Despite decreasing curricular attention, the number of harmful and fatal compounding errors has been relatively very small. For example, it was not publicized in June 2001 that hundreds of

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thousands of patients lived and healed as a result of compounded anticancer drugs, antibiotics, and TPN on the same days 3 patients (yes, that’s 3 too many) died of meningitis in California from injection of non-sterile compounded betamethasone.

**Quality Initiatives Outside Academia**

During the 1990s, the American Society of Health-System [Hospital] Pharmacists published 3 comprehensive guidelines and assistance bulletins on good pharmacy compounding, and the *US Pharmacopeia* (USP) created 4 specialty chapters, which are currently in revision or new proposal stage.\(^5\)\(^8\) To promote quality in rapidly growing outpatient compounding, the *International Journal of Pharmaceutical Compounding* was founded in 1996 by former pharmacists professor, Dr. Loyd V. Allen, Jr. Those publications followed shrinkage of compounding content in the historic *Remington's* text and cessation of the classic text, *Dispensing of Medication*, 9 editions of which were published from 1935 to 1984.

**Regulation and Credentialing**

Since the early 1990s, most national pharmacy practitioner organizations have asserted compounding is an intrinsic professional practice to be regulated by state boards of pharmacy. The FDA can regulate compounding under the adulteration and misbranding provisions of the 1938 Food, Drug and Cosmetic Act, but it usually defers to state boards of pharmacy.\(^9\) Ironically, state boards of pharmacy do not have enough expert inspectors to enforce compounding practice standards, and most boards of pharmacy do not examine the compounding proficiency of their licensure candidates.

The FDA is concerned that compounded preparations are likely to have lower quality than manufactured products,\(^2\)\(^9\) and particular FDA personnel are aware that compounding instruction is highly variable in pharmacy schools. (The author has personally heard both concerns from key FDA officials during USP-related meetings.) It would hurt the pharmacy profession if the FDA were to require a label like the following on all pharmacist-compounded preparations: *This preparation compounded by your pharmacy has not been evaluated for safety and effectiveness by the Food and Drug Administration.*

Certification of compounders by the Board of Pharmaceutical Specialties and accreditation of compounding pharmacies by a joint commission of national pharmacy organizations was proposed at Pharmacy Compounding Stakeholders Forums hosted by the USP in 2001 and 2002. Board certification might be earned at different levels, eg, pharmacists would pass different theory and skills exams to compound topical versus oral versus sterile preparations.

**Will Academia Sustain Compounding?**

Over the past 4 decades, pharmacy schools have phased out the mortar and pestle for the stethoscope and sphygmomanometer. Despite that trend, 5 of the current 37 NAPLEX® competency statements in the Candidates Review Guide (www.nabp.net) include the word “compounding” and 2 others imply it. Those 19% of competencies signal that new graduates should expect, and the NAPLEX® does expect, adequate compounding instruction in pharmacy school.

Minimal competency in nonsterile and sterile compounding practices could be taught in 2 one-semester laboratory credits, or 1% of a 200-credit PharmD curriculum. However, judging the important feels, sights, smells, and sounds of compounding requires up close and in-person, rather than online, teaching. The "educational care of pharmacy”\(^10\) should include introducing students to the main clinical purposes and basic skills of the profession's oldest, most symbolic, and still essential specialty. Students should not learn more about compounding from PCCA's $200 two-day "boot camp" than from 4 expensive upper division years in our schools.

(Dr. Newton is Chairman of the Sterile Compounding committee of the United States Pharmacopeial Convention's 2000-2005 Council of Experts.)

**References**


