

EDITORIAL

Pharm.D.-only Investigators Are Critical to the Profession: Let's Preserve the Fellowship as an Equally Important Way to Prepare Future Clinical Pharmaceutical Scientists

Or the Case Against the “All-Ph.D.”

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Let us begin with truth in advertising: neither of us has completed a research fellowship or a Ph.D. So, despite (or because of) our “career-development shortcomings,” we felt compelled to comment on the current state of affairs and the direction that leaders in clinical pharmacy have chosen in recommending the preferred method of preparing the clinical pharmaceutical scientists of the future. There appears to be a sheep-like momentum here, as two national groups of Pharm.D.s (no less) have warmly embraced the Ph.D. route as the preferred method: first, an American Association of Colleges of Pharmacy (AACP) task force,¹ and now, somewhat surprisingly, the American College of Clinical Pharmacy (ACCP).² Having served as presidents of ACCP in our younger days, we would not have predicted this turn of events when ACCP was founded. We will attempt to convince at least some of the readers of *Pharmacotherapy* to resist these recommendations and preserve the Pharm.D./fellowship route — on at least equal footing with the Pharm.D./Ph.D. route. If we can convince at least some of the more accomplished Pharm.D. investigators to oppose the Pharm.D./Ph.D. direction, perhaps they will serve as role models for some of our smarter students to follow.

Why Preserve the Fellowship Route?

Foremost, having those with only the Pharm.D. degree (without a Ph.D.) engaged in meaningful scholarship and clinical research is best for the profession of pharmacy. Before the clinical pharmacy movement, there were relatively few pharmacist role models in academia. Rather, nonpracticing basic science faculty taught what little clinical therapeutics was contained in the curriculum. Most students pursue pharmacy school because they want to practice pharmacy, not because they want to perform basic

laboratory research or even clinical research. When we entered the profession, there were very few real clinical role models in academia and even fewer clinical pharmacy researchers. With the growth of clinical pharmacy faculties in colleges of pharmacy, the dearth of clinical pharmacy practice role models improved somewhat; actual practicing pharmacists, some with the Pharm.D. degree and some without it, moved from the bedside to the classroom, and students could realistically envision themselves following the faculty member's lead as a clinician pharmacist. These were some of the individuals who inspired both of us to pursue our own career tracks (for better or worse). Research, as a natural extension of practice in academic health centers, came next for these early clinical pharmacists — yet most remained vivid clinical role models for pharmacy students. They were pharmacists, through and through. With the task force recommendations in mind, we are trying to imagine the clinical pharmacy departments of the future in research-intensive institutions — no Pharm.D.-only scientists? Or if there are remnant Pharm.D.s (tenure can be forever), are they second-class citizens in this new academic paradigm? It doesn't take much imagination to envision a reemergence of the old ways and a *déjà vu* of sorts: an entire department of Ph.D.s (now in so-called clinical pharmacy departments) who do not practice clinically and perhaps have not ever practiced clinically and who are thus not realistic role models for pharmacy students.

The model of M.D.s performing research has served the profession of medicine relatively well. Here, M.D.-only scientists retain their “label” as physicians first (rather than scientists) and seem to be realistic role models for many medical students. When they publish in the *New England Journal of Medicine*, the world knows that medicine is generating new knowledge from *within* the clinical sphere of the medical profession, and

this fulfills an important element of the profession while moving it forward. There is a halo effect surrounding these individuals in medicine, and the profession of medicine profits from it immensely. Of interest, even those with M.D./Ph.D.s are recognized as *physicians* doing “medical” research. But for pharmacy, the situation, at least at this time, appears different for some reason. Pharm.D./Ph.D.s are almost always labeled as “scientists” rather than pharmacists, and there is little or no discernible “halo effect” on the profession of pharmacy. It’s as if the Pharm.D. degree alone (or even with the Ph.D.) doesn’t quite cut it in terms of being a real scientist. While others may choke on saying “Pharm.D.” at professional and scientific meetings (or cocktail parties), we revel in it. When Pharm.D.s (only) publish in high-impact journals, it reflects positively on the profession of pharmacy and its contributions to the sciences underlying health care. Stick a Ph.D. after the Pharm.D. and the world assumes it must be a biochemist or pharmacologist who has made the discovery. We really like the concept of at least some Pharm.D. scientists training Pharm.D. fellows to become scientists and providing a realistic role model that helps generate a cadre of “pharmacy scientists” who advance the science on which our profession is based. Retention and growth of this model will help advance the profession of pharmacy if these pharmacy scientists are leading their field of investigation.

We certainly are not against the Pharm.D./Ph.D. route for preparing clinical pharmaceutical scientists. Some of our most valued collaborators and colleagues are Ph.D.s (a few are even friends!). No, what is irritating is the use of the words “preferred” or “optimal.” In our experience, individuals trained by these two different routes are often complementary in their skill sets — with the Ph.D. individual having somewhat better

technical and laboratory skills and the Pharm.D., fellowship individual having better clinical and pathophysiological insights. But, just as often, they end up the same: the barriers to academic and scholarly success listed in the reports of the two task forces affect both types of individuals, regardless of how they got there. For both, it's difficult to obtain competitive funding from national agencies; both need strong mentorship and support to be successful and, crucially (and, in our mind, perhaps most importantly), both need to be inquisitive with the proper personal qualities such as perseverance and zeal to become successful. The ability to identify the right question and conduct a definitive line of investigation to answer it is also quite helpful. This is where an ounce of intellect, a sense of inquisitiveness, and a passion for innovation are indispensable. It is doubtful that these traits commonly typify the student who comes to pharmacy school with a career at the corner drugstore in mind, which is a major concern if this is where we are looking for the next generation of clinical pharmaceutical scientists.

There are also significant problems and barriers that should not be overlooked when launching lemming-like into this "preferred Pharm.D./Ph.D. route." Many individuals hope that the recent effort by the federal government to stimulate translational and clinical science will change this, but we are skeptical: the track record of M.D./Ph.D. programs in medicine is not incredibly impressive, because most of these individuals historically leave practice and clinical research entirely. Success at being awarded grants from the NIH is nearly equivalent for M.D.s (alone), M.D./Ph.D.s, and Ph.D.s in colleges of medicine.³ In addition, the length of training is problematic and is expected to worsen, particularly with many or most entering pharmacy students now having an undergraduate bachelor's degree and the looming possibility of a PGY1 residency being required to

practice in the future: “*Mom and Dad, it’s going to take me 13–15 years (4 B.S., 4 Pharm.D., 4–6 Ph.D., and 1 residency) to be the clinical pharmaceutical scientist you wanted me to be!*” We are likewise skeptical that the Pharm.D./Ph.D. route can supply the need for clinical pharmaceutical scientists. Data cited in the ACCP commentary² appear dismal: “*50 [Pharm.D./Ph.D.] students have graduated over the past 5 years, with approximately 50% pursuing faculty or postdoctoral positions....*” Stated another way, Pharm.D./Ph.D. efforts thus far appear to have resulted in, at most, five faculty members (or postdocs?) per year in the nation. Yikes. Certainly, the profession of medicine is not shortsighted enough to rely only on the output of M.D./Ph.D.s to fulfill the need for clinical and translational scientists, nor can we find that they feel this is the preferred route.

So somebody tell us, what, exactly, is wrong with the vision of having both types of individuals, trained by different routes, *equally* valued without one method being “preferred”? Please know that the answer “from on academic high” will not affect either of us, as we will be long retired (in the south of France — at least for one of us) when the negative ramifications of this decision are evident. But so will most of those responsible (hopefully not in Provence), so perhaps that explains their *laissez-faire*.

Arguments Against the Pharm.D./Fellowship Route

“*I can’t recruit fellows anymore.*” Although it does strike us that the glory days of fellowship recruiting may have waned somewhat, the better question is, Why? One reason usually given is the pharmacist shortage, resulting in a highly competitive marketplace, high salaries, and multiple opportunities for new pharmacy graduates. This

is mostly bunk. If significant, then one would have to explain why 20% to 30% of new graduates from many colleges of pharmacy decide to do a PGY1 residency and why the number of residents and residencies continues to grow rather impressively. The answer is simple: *That's where the role models are.* Research (e.g., tenure track) clinical pharmacy faculties typically do not practice; hence, few oversee many, if any, clerkship students or residents. They sometimes lecture, but only a little. Tenure-track Pharm.D.s are rapidly becoming non-clinical practice role models for pharmacy students. Non-research clinical faculty members interact with pharmacy students earlier because of the new accreditation standards, have them the entire P-4 year, maintain practices, and carry much of the lecture load in many colleges. They are the actual role models, and students appropriately follow their lead to pursue residency training, despite the lure of financial reward in entering the workforce immediately after graduation. Students and residents would once again return to pursue fellowship training if the role models were in place. With proper and visible role models, it is our contention that it would be much easier to recruit Pharm.D.s into fellowships than into Ph.D. programs. Because it is rarely articulated that the probability of annually earning seven figures is greater in a clinical pharmacy research career than in traditional practice, the six-figure salary for a 40-hour week looks more financially attractive as well.

“Pharm.D.s (without the Ph.D.) can't get R01s.” Well, in our experience, there is certainly no inherent bias on the part of the NIH against Pharm.D.s; the science stands on its own merit, independent of degree. Pharm.D.s are fully eligible, so it is a matter of your idea, your plan, and, ultimately, your productivity. And these days, it's hard for anyone to get an R01, even if they have three Ph.D.s. But we think the unstated point in

this argument is that Pharm.D.s with fellowships do not have the proper grounding or rigorous training (compared with those having Ph.D.s) to successfully compete for NIH funding. *But they can.* Proper coursework during the fellowship should be in place, and concurrent master's degrees could be considered (K30 master's or certificate program in Clinical Science is a good example); to complete a fellowship, 2–3 years of training are clearly necessary. Some would ask, “*If you are going to go through that rigor for that length of time, why just not go and get a Ph.D. (read: a real scientific degree)?*” We would respond, “See part 1 of this editorial.” Also, is the R01 the “be-all and end-all of research”? Have we outsourced our promotion and tenure decisions to the NIH? We can understand why competitive funding should be a goal of young clinical pharmaceutical scientists, where one's peers can render judgment on proposals shaped by one's own ideas and science. It is the currency understood by medicine and the basic sciences. However, making important advances, sharing your results, and assessing their real impact on the clinical care of patients should be the goal. Pharm.D.s with fellowships should – and can – be well positioned to do this.

Much has been made of the relatively small numbers of Pharm.D.s who are principal investigators on NIH grants, compared with their basic science Ph.D. colleagues. Although this is true, we grow weary of the unstated point of using these data: that Pharm.D.s (without the Ph.D.) are *not capable* of successfully competing at the national level. There are many reasons why this is not the proper reasoning, including that clinical (applied) research has not always fit neatly into prior NIH funding streams. Historically, faculties in pharmaceuticals were not successful in attracting NIH funding because drug delivery was not given appropriate priority by the NIH. Faculties in

pharmacy administration are joined with us as the bottom-feeders of the NIH funding pool, yet nearly all of these individuals have Ph.D.s. And alluding to the point that we are incapable minimizes the scientific contributions of Pharm.D.s, many of which (given our small numbers compared with physicians and Ph.D.s) are substantial and responsible for noteworthy changes in the way drugs are used in humans (most of these contributions were probably not funded by the NIH). Frankly, we are quite proud of the progress made during the past 30 years in this regard.

“Fellowships vary in length and lack enforceable standards.” Yes, and so do green beans and Ph.D. programs. Cream rises to the top in both fellowships and Ph.D. programs. Our recommendation is to buy the green beans that taste the best, regardless of degree. If fellowship training can be reinvigorated, it may be logical at some point to consider an accreditation process of sorts, perhaps by a group such as the Commission on Credentialing. Moreover, it may be wise to reconsider the current ACCP/AACP fellowship guidelines to make sure there is adequate rigor in the standards. However, the current problem (unlike the profession of medicine) is that there are no teeth in the standards. At this time, money flow for fellowships (unlike pharmacy PGY1 residencies) is not dependent on accreditation or approval, and therefore, all that remains is altruism for one to adhere to the guidelines.

“Graduate students cost the PI less than fellows.” There are few ways to look at this argument: (1) cheap is good because you don't have to pay so much or (2) you get what you pay for. It is true, graduate students will generate revenue for an institution in the form of tuition if they do not have a research or teaching assistantship, and fellows cost money in the form of a stipend or salary. We daresay that most research programs

successful enough to consider fellowship training should have adequate funds to support a Pharm.D. fellow. We would also urge institutions to provide incentives in this regard, such as shared funding arrangements. More to our point, dedication of financial support for Pharm.D. fellow positions is simply the right thing to do for the profession – and not simply a dollars and cents issue.

A final thought is that pharmacy schools need to reach out beyond the current source of pharmacy school applicants, to attract students who have an innate interest in and passion for science, and use this to supplement the current applicant pool. Let the research-intensive schools go to top undergraduate colleges and advertise a career in science that has the professional underpinnings of pharmacy. Let us in this way attract a new substrate into the profession, instead of trying to convince a few Pharm.D. students to pursue a career in science when they were never so inclined. Perhaps we are looking under the light for the lost keys when what we should do is attract some different talent to pharmacy schools. The idea is that these students would first become pharmacists, and then scientists, and never leave the clinical profession of pharmacy.

Recommendations

1. We propose a national effort to reinvigorate research fellowship training for Pharm.D.s as an important way to prepare future clinical pharmaceutical scientists. It is not our aim to undermine current efforts to create Pharm.D./Ph.D. programs in the clinical sciences. In fact, we support a strong and parallel effort to create and sustain Pharm.D./Ph.D. programs. We simply are in favor of having both routes — without one

way being preferred — and strongly feel this is best for the profession as a whole. Simply put and like medicine,⁴ we need multiple pathways.

2. We ask the profession to reanalyze current fellowship guidelines to ensure they reflect the time and rigor needed to prepare future clinical pharmaceutical scientists; the need for a concurrent M.S. degree or standardized curriculum in clinical research should be contemplated.
3. We encourage current clinical pharmaceutical scientists to vigorously engage with Pharm.D. students and residents as mentors and role models.
4. Deans of colleges of pharmacy must work to truly understand clinical and translational pharmaceutical research; they must nurture and invest in it. In turn, clinical pharmacy scientists and faculty must apply and compete for NIH awards. As federal funding priorities move toward clinical and translational science, there is a clear opportunity for clinical pharmacy scientists that has not always been visible.

Epilogue: There was a great deal of fortuitousness when Gerhard Levy, Pharm.D., was *not* awarded a Ph.D. degree after his pharmaceutics education at the University of California in the 1960s. The impressive body of research that he subsequently published under the Pharm.D. imprimatur opened doors for Pharm.D.s like us to put our work forward as credible scientists. Now is not the time to start closing those doors for pharmacists who will follow our generation.

References

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Acknowledgments: Dr. Evans is funded in part by NIH R37 CA36401, NIH R01 CA78224, NIH U01 GM61393, NCI Cancer Center Support grant CA21765, and ALSAC/St. Jude Children’s Research Hospital; Dr. Bauman is funded in part by DoD Contract W81XWH-07-1-0445 and the Vahlteich/UIC research fund.