VIEWPOINTS

Murkiness in the Channels of Distribution of Pharmaceuticals

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Pharmacy curricula are packed with important required and elective coursework. The worth and importance to the academy of these courses and the dedicated faculty members providing these courses simply cannot be overestimated. There seems to be an overabundance of necessary curricular components and precious little surplus time to cover what needs to be added.

However, there is one educational segment that appears to be sorely under addressed, or frankly missing entirely from the curricula. There are significant and increasingly disturbing problems within the drug manufacturing, regulatory, payment, and access processes regarding medications in the United States and beyond. Issues that have come to light in the past years include medication counterfeits, breakdowns or total absence of quality assurance (eg, unsterile water used in processing, production line problems, employee contamination of products, drug contamination, drug batch mix-ups), fraud and abuse in pharmaceutical pricing by manufacturers (brand name and generic), expanded demand for a compromised supply chain of manufactured products. But just as important as any of these problems, is the need for leadership at all levels to impact these pressing, life-threatening problems. Are we in the Academy providing students with the awareness, knowledge, and skills that would allow them to step into these chasms and make a difference by helping to eliminate or ameliorate these major concerns?

Troubles Within the Channels of Distribution

The past several years have proven to be challenging when considering the problems that have surfaced within the drug manufacturing, drug promotion, drug payment, drug regulation, and drug use processes.

Drug recalls. Drug recalls and manufacturers' actions regarding the recalls have been frequent news items in the past several years with totals approaching 1,800 in 2009.[1] In the guise of cost-cutting, quality control personnel with necessary expertise and other staffing levels have been gutted with unfortunate and predictable results.[2-4] Recalls of McNeil Healthcare and Johnson and Johnson Merck products have reached double digit levels.[5] A "phantom" recall of Motrin in 2009 by McNeil was alleged to have occurred and involved having company personnel buy up existing stocks of the drug off store shelves to avoid a formal recall.[6]

These recalled brands have been among the most trusted consumer products for decades. It is bitterly ironic that the Johnson and Johnson brand and preceding company set the bar so high with their response to the 1982 Tylenol poisoning and murders. Johnson and Johnson received praise for their remarkable response to the crisis, which included issuing an immediate recall of every bottle of Tylenol, the most popular consumer branded product in the United States.

US Food and Drug Administration. The FDA has been under fire for a significant period of time for lax oversight of the drug manufacturing milieu in the United States.[7] One specific concern is the source of precursor chemicals, specifically active ingredients imported from China and elsewhere. The FDA simply does not have the resources to monitor chemicals obtained outside the country.

The FDA has published a strategic priority document for the next 5 years (2011-2015).[8] In the document, challenges presented by globalization include a staggering and increasing volume of imported products (for 2010; 130,000 importers at approximately 300 ports of entry), more foreign facilities providing agents for the United States (300,000 plus facilities in over 150 countries), incomplete regulatory information about supply chains, and corporations lacking accountability.

The issues facing the FDA are incredibly complex; they certainly will not diminish in the future. More and more pressure is being exerted on the FDA from all sides. At this juncture, there has not been a dramatic influx of funds to meet the expanding requirements placed on the agency. Few would deny that this is a crucial time for the FDA with new expectations, limited financing, increased pressure, and diverse views about what the administration's responsibilities should be. Now a biased question: why are pharmacists not considered to a greater extent for the FDA Commissioner position? Decades ago, Dr. Jere Goyan served with distinction, but he was the last pharmacist to serve in this role. Pharmacists serve in many exemplary capacities in the FDA; they also could and should be considered to serve as FDA Commissioner.

Reimbursement Fraud. Unconscionably and unbelievably, billions of dollars in payment fraud schemes on

the part of pharmaceutical manufacturers (both brand name and principally generic companies) have been recovered on behalf of various states and the US federal government.[9] Almashat and colleagues performed a 20-year review of fraud claims and awards levied against pharmaceutical manufacturers.[10] One hundred sixty-five settlements comprising $19.8 billion in penalties occurred during a 20-year period between 1991 and 2010.[10] Of this, 73% of the settlements (121) and 75% of the penalties ($14.8 billion) had occurred just in the previous 5 years.

Medicaid and Medicare drug benefits for program recipients have been harmed due to this greed on the part of manufacturers and distributors of pharmaceuticals. Many of these lawsuits are currently in play as well, with more settlements sure to come. Whether these settlements will make a difference (they are enormous sums of money) or simply be viewed as the cost of "doing business" remains to be seen.

These manufacturers' related fraudulent allegations and actions are not restricted to the United States, in late December 2010 European Union officials late in 2010 raided several pharmaceutical company offices, probing for evidence of price manipulations between brand name and generic companies who were colluding to keep generic drugs off the market in Europe.[11] The European Commission confirmed that unannounced inspections in the pharmaceutical sector had occurred.[12] These illegal actions allegedly have occurred on both sides of the Atlantic.

Drug Shortages. Recent and continuing drug shortages in health systems and other settings are disturbing and have challenged practitioners as never before. Demand, inability to meet demand, and poor planning have no doubt affected manufacturers' capabilities. Drugs in short supply such as epinephrine, hydromorphone, propofol, and cancer chemotherapies threaten patients' wellbeing.[13,14] The American Society of Health-System Pharmacists (ASHP) has developed guidelines to deal with such shortages.[15]

Need for Leadership

Among the requisite skills sought when considering persons to hire for important management positions in the pharmaceutical industry and drug regulatory arena are technical competence, appropriate training, and academic degrees that would enable them to accomplish the tasks associated with the position. Perhaps what are most needed, however, are leadership skills along with ethics, transparency, and fairness, among many other personal attributes. As pharmacy educators, our students amaze us daily with their skills and capabilities, and they may be the ones needed to solve the aforementioned dilemmas. There are many opportunities for pharmacists in the channels of distribution; we in the academy and certainly our students should consider how we can help clear up the murkiness that exists.

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