



FIGURE 9.3

PCCA lollipops with compounded medicines. (From PCCA. With permission.)

the “captains of our pharmaceutical drug supply chain.” In Chapter 10, we review selected people who, in the past, have combined a vision for what’s needed with innovative actions to make a difference.

DRUG SHORTAGES

Poor public policy (or at least one that is reactionary) and excessive regulations have the potential to create drug shortages. Under Title I of the Drug Quality and Security Act, the definition of a *compounding manufacturer* versus a *compounding pharmacy* has the potential to be very problematic. As we mentioned before, there are a significant number of small to medium compounding pharmacies that produce compounded medicines “for office use” for hospitals and medical facilities with patients that have physician prescriptions. I have heard several times from owners of compounding pharmacies that they spend a significant portion of their discretionary income on compliance to regulation activities, including lawyers, instead of additional capacity to compound medicines. There is a real possibility that if they are deemed manufacturers and subject to the current good manufacturing practices (cGMP), they will exit the business and shutter their capacity. Patients who rely on their compounded medicines will have to wait for their medicines or stand in a line for rationed supplies. Another big reason is the cost of litigation when mistakes are made. The more regulation, the greater the cost of litigation and risk mitigation.