



California State Board of Pharmacy
1625 N. Market Blvd., Suite N219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
EDMUND G. BROWN, JR., GOVERNOR

May 28, 2013

Transmitted via email to

Representative Henry Waxman, Ranking Member, Energy & Commerce Committee

Representative Frank Pallone, Jr., Ranking Member, Health Subcommittee,
Energy & Commerce Committee

RE: FEDERAL EFFORTS TO SECURE DRUG DISTRIBUTION SECURITY
Comments of the California State Board of Pharmacy on
H.R. 1919, "Safeguarding America's Pharmaceuticals Act of 2013"

Dear Mr. Waxman and Mr. Pallone:

I write on behalf of the California State Board of Pharmacy (Board). We appreciate this opportunity to submit our written comments on H.R. 1919, titled the "Safeguarding America's Pharmaceuticals Act of 2013." Our comments pertain to H.R. 1919 as it was reported out of the Energy & Commerce Committee on or about May 15, 2013. We write to express our concern that this bill, as currently drafted, does not do enough to promise an increase in the security of the drug distribution supply chain, while at the same time preempting the California pedigree law and tying the hands of states like California to regulate wholesalers.

We want to first thank you and the bill's authors and co-sponsors for acknowledging and taking on the challenge of increasing drug supply chain security. We understand that it is not an easy task to balance the need for increased security against a desire to avoid adding unnecessary costs and possible interruptions to the supply chain. We also recognize and appreciate just how much effort has gone into the bipartisan and bicameral effort to reach agreement on legislation necessary to achieve needed improvements in drug supply chain security. Finally, we agree that it would be ideal for the subject of supply chain security to have a federal legislative solution, as this is a subject that would be more ideally regulated at the federal level than by the states.

However, we believe H.R. 1919 does not promise the kind of robust supply chain security that is necessary to ensure adequate patient protection, and is not an adequate replacement for the California pedigree law that, absent this bill, will go into effect beginning in 2015. Our reasons for this are various; many of these have been covered in our comments on prior legislative drafts. In the interest of brevity, and because we want to get these comments to you in time for them to be considered along with any action that might be taken on H.R. 1919, we will keep this iteration of our comments relatively succinct. Please find enclosed our letters dated April 26, 2013, on the draft of the bipartisan Senate bill released for comment at that time (since introduced in much the same form as S. 957, and combined with S. 959), and November 7, 2012, on the bicameral DDS Draft that was at that time sent out for comment, which we hereby incorporate by reference.

In brief, our primary though by no means only objection to this draft is that it promises no certainty that we will ever see the end-to-end, full participation, electronic track-and-trace system monitoring drug distribution security at the unit (package) level, with trading partner verification and validation and the resulting protections against counterfeit and adulterated products, that has been the recommendation of the FDA since its Counterfeit Drug Task Force convened in 2004. This bill leaves the development of any such system to some future rulemaking, to be published no sooner than 2027, effective 2 years later, and even then this legislation requires no particular outcome of such rulemaking. We have no confidence, given the history of the Prescription Drug Marketing Act of 1987 (PDMA), that this deferral will result in any increase in security. While we have also expressed concern (see April 26, 2013 comments) that Section 3 of the Senate draft should be improved and strengthened, and that it should not take an additional 10 years to get to the system outlined in that section, we far prefer the relative certainty of the Senate model to this draft. There has already been substantial agreement that a uniform track-and-trace infrastructure is needed to ensure supply chain security, and many participants in the supply chain are already well on their way to implementing that infrastructure to comply with the California timeline. We believe that without placing a definite outcome and a date certain into the legislation, all of that momentum will be lost and all of that industry investment will be wasted. We believe the public deserves a robust supply chain security system, and we further believe that the industry needs the certainty of firm deadlines and objectives in order to adequately plan their capital investments.

Of nearly co-equal importance, we also object, for many of the same reasons stated in our November 7, 2012 letter, to the language in Section 585, subdivision (b) (and/or elsewhere), that has the effect of making the proposed national wholesaler licensure standards *both* a “floor” and a “ceiling” on the independent authority of states to regulate wholesalers. We support national minimum standards for wholesalers, and also support federal licensure of distributors in states that do not provide such licensure. But we strongly believe that states should remain able to enact and enforce state-specific provisions that go above and beyond national minimums, to respond to more local issues and also to later developments requiring more immediate action. We are happy to work with you further on this topic, and to share examples of why we believe it is so crucial for states to retain flexibility and additional authority with regard to regulating wholesalers.

One such example would be the difficulty experienced in California and other states over the last few years with “gray market” purchase and re-sale practices by (secondary) wholesalers. California has seen a dramatic uptick in re-sales of drugs that are in short supply, as wholesalers and their trading partners evade typical drug shortage allocations by purchasing from pharmacies who become de facto “purchasing agents” for the secondary wholesalers, acquiring drugs from a primary wholesaler for the purposes of re-sale to the secondary wholesaler, which in turn re-sells the drugs to another secondary wholesaler or to an end user. These practices can result in further increases in the already-increased prices of shortage drugs, in further distortions in supply, and in supply chain vulnerabilities from the multiple purchases/re-sales. Some of these problems have been documented in a bicameral investigation report by Senators Rockefeller and Harkin, and by Representative Cummings, which addressed the problem and possible solutions. A copy of this report is available at <http://cummings.house.gov/cummings-releases-joint-report-gray-market-drug-companies>. This kind of unexpected and unprecedented conduct by wholesalers presents a new challenge, that has not been anticipated by previous licensing schemes (or the framework in the present draft). California and other states will have to devise new regulatory language that is able to better handle these kinds of market innovations. We must retain the flexibility to do so, and to add to the federal minimums when these kinds of situations come up. Under the language of H.R. 1919, we will not have the necessary flexibility and authority to do so.

Conclusion

For these reasons, as well as those spelled out in more detail in the enclosed letters, we cannot support the current draft of H.R. 1919, although we believe and reiterate that a federal model is ideal. We do not believe that additional drug security can await the possible development of future standards some 14 or more years after enactment. We believe the security of the drug supply and the public's trust in that drug supply are threatened, and any further delay simply adds to the scope of these threats.

We also believe that the endpoint should be a national end-to-end track-and-trace system that is worthy of any additional delay, and adequate to replace the California model. We believe the necessary components of any such system include: participation by *all* industry partners; in passing and receiving electronic drug "pedigree"/chain-of-custody data as to *all* prescription drugs; to which data all shipments and deliveries are validated; by tracking and validating shipments at the (saleable) unit level at each stage of distribution. We believe this proposal fails to fully articulate the system first envisioned by the FDA.

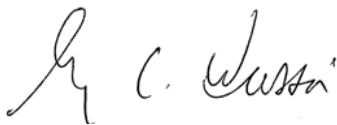
Finally, we remain concerned that the hands of California and other states with robust programs to license and regulate wholesale distributors will be tied by the national licensure standards section(s) of the bill. We would encourage you to adopt a model wherein the federal legislation sets a floor for wholesaler licensure standards (and provides for federal licensure where states do not offer same), but not a ceiling.

We again commend you for your leadership on these vital issues of national security. Thank you also for your willingness to hear our input. We look forward to our continuing work together to secure the nation's drug supply. Please feel free to contact the Board any time if we can be of assistance.

The best ways to reach me are on my cell phone, (909) 633-2574, or by email to stanweisser@aol.com. You may also communicate with the Board's Executive Officer, Virginia Herold, by telephone at (916) 574-7911, or by email to virginia.herold@dca.ca.gov.

Thank you again for your efforts. We are grateful to all of you, and hopeful that we are nearing a strong federal system for regaining a strong pharmaceutical supply.

Sincerely,



STANLEY C. WEISSER, R.Ph.
President, California State Board of Pharmacy

Enclosures: April 26, 2013 Board comment letter
November 7, 2012 Board comment letter