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

April 26, 2013

Transmitted via email to drugdistributionsecurity@help.senate.gov

Senator Tom Harkin, Chairman, Committee on Health Education Labor & Pensions

Senator Lamar Alexander, Ranking Member, Committee on Health Education Labor & Pensions

Senator Michael F. Bennet, Member, Committee on Health Education Labor & Pensions

Senator Richard Burr, Member, Committee on Health Education Labor & Pensions

RE: FEDERAL EFFORTS TO SECURE DRUG DISTRIBUTION SECURITY
Comments of the California State Board of Pharmacy
Draft Proposal to Improve Drug Distribution Security – released/posted for stakeholder comments April 19, 2013; comments due to the above by April 26, 2013; 6:00 p.m.

Dear Chairman Harkin, Ranking Member Alexander, Senator Bennet, Senator Burr, members of the Committee and the Drug Distribution Security working group:

I write on behalf of the California State Board of Pharmacy (Board). We thank you for this opportunity to submit written comments on the Draft Proposal to Improve Drug Distribution Security ("DDS Draft"), made available on April 19, 2013. We recognize and appreciate how much effort has gone into developing this bipartisan proposal, which has addressed many of the difficult questions that were raised by the November 2012 draft, and which is improved since the November 2012 draft. We also recognize and appreciate that the DDS Draft was clearly written with California's interests in mind, and thank the entire working group, particularly the members of the California delegation in both houses, for considering and promoting California's unique but shared perspective, and for our collaborative relationships. We have been pleased to work closely with the staffs of the committees and the members, and this has been gratifying.

We will reiterate herein some of what has been expressed in our prior comments, but will try to be as brief and direct as possible in addressing the particular legislative proposal now under consideration. Because we refer to some of the points raised in our longer set of comments dated November 7, 2012, a copy of those comments is enclosed and incorporated by reference.[1]

[1] We have tried to keep these comments succinct. Given the time constraints, and the number of comments we expect you will receive, we have not attempted to make this document comprehensive. Instead, we look forward to the ongoing opportunity to engage with you on the details. Also, many of the comments submitted in our November 7, 2012 letter remain applicable, so we refer you to that document. To the extent possible, we ask that you not treat these comments as exhaustive, that we be allowed to communicate any later-realized comments to the working group in follow-up communications, and most important, that you not presume that our silence, relative silence, or lack of objection to any concept or provision indicates that we support and/or do not oppose that concept or provision. We do not intend any such silence to indicate assent.
Also, the order in which comments are presented is not necessarily meant to signal their importance.

We are prepared at this time to offer the Board's reserved support for the direction offered in the DDS Draft proposal released April 19, 2013, and believe that with some modifications, this proposal offers the potential for significant public protection. We are by no means satisfied with the current form that the draft proposal takes, and believe it represents a significant step backward from the California model for electronic pedigree/track-and-trace. We are especially dismayed by the additional delay that is built into the various stages of the proposal. We believe regulators and the industry can and must do better than this, and that the public has a right to demand more. It has been over 25 years since the Prescription Drug Marketing Act (PDMA) was signed into law. We should not have to wait another 10 years for full implementation of this latest attempt to secure the supply chain, and/or it should be possible during that period to more closely mimic the California model. In the comments that follow, we will identify a few key areas where we seek improvement.

However, as we have repeatedly stated, we strongly support the principle of a federal law in this subject area, and a nationalized model that increases the security of the entire national supply. We believe that this proposal, particularly Section 3, while it is less than an adequate replacement for California's pedigree law, will make some positive difference in supply chain security, and we are prepared to treat this as an incremental improvement upon which we can still hope to build with continued engagement in this subject area. We also recognize and appreciate the bipartisan nature of this proposal, and the tremendous effort expended to reach a form of consensus. We do not wish to let the perfect be the enemy of the good, or to presume that we hold all of the answers.

Therefore, on balance, while we cannot express enthusiasm for the proposal as drafted, nor do we actively oppose its passage. We recognize that the federal government has a primary role to play in this national security issue, and welcome this expansion in the federal portfolio in this area. We look forward to the continuing opportunity to engage in this shared project.

We should be clear, however, that our support or lack of opposition is entirely conditioned on the continued inclusion of a robust, definite, and self-executing Section 3. We view this as the most important section of the proposal, and we will not support any effort to delete, weaken, delay, or make conditional or dependent on external events, the provisions of Section 3.

General Comments on the DDS Draft

In the interests of time, we will not repeat a lot of what was expressed in our November 7, 2012 comments, and will simply refer you to that document. However, it is worth repeating very briefly a few of the general points made in those prior comments, including:

- It is not only the people of California that stand to benefit from implementation of California's electronic pedigree requirements, as we believe the entire supply chain will be strengthened by compliance with the California requirements; certainly, the pharmaceutical supply chain is in need of additional security features;

- California's law has been in place since 2004, and is scheduled to go into effect on a rolling timetable between 2015 and 2017, so there has been plenty of notice and opportunity for members of the supply chain to come into compliance;

- Many members of the pharmaceutical supply chain are already on track to meet the 2015-2017 timeline for compliance with California's law, and we believe that those "early adopters" should get the benefit of their voluntary compliance;

- We must assess this federal proposal as a substitute for California's law; and

- As the FDA has repeatedly expressed, we believe that any federal track-and-trace solution should include at least: 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 the shipments and deliveries are validated; by tracking and validating shipments at the (saleable) unit level at each stage of distribution.

By these latter two standards, the DDS Draft falls short, in both timing and substance. Of greatest concern, not only does the DDS Draft push the timeframe for Section 3, the only part of the proposal that even approximates the California model, out for 10 years, even at that point there is significant underutilization of the serialization technology that is required by the proposal. We know from our experience in California that legislation in 2008 which pushed the (previous) implementation date back from 2011 to 2015-2017 resulted in the suspension of the momentum, effort and commitment to compliance by supply chain members for several years, so setting the key federal implementation phase out 10 years following enactment is very problematic.

Additionally, the proposal does not adequately specify or require that each shipment (at the unit level) be *automatically validated* to transaction data from trading partners. Nor does the draft seem to ensure full chain-of-custody visibility for downstream trading partners. We also believe that the proposal does not adequately ensure full participation by all members of the supply chain. For instance, we understand the reasoning behind the allowance for some supply chain participants (particularly small dispensers) to seek waivers from the requirements of the proposal. However, we do not believe that supply chain security can be adequately assured without full participation. We are dismayed that dispensers, who are on the front lines of patient care and are therefore closest to the potentially devastating effects of counterfeit, adulterated, or otherwise unfit drugs, might not take advantage of the additional security promised by the proposed system. More to the point, we are concerned that any such loophole(s) in the closed system can and will be exploited.

Specific Comments on the DDS Draft[2]

Again, we will keep these comments short, and refer you to our November 7, 2012 letter, as many of the specific comments contained in that document remain applicable. We will limit these comments to just a few of the more significant and noticeable changes we would suggest, in the general order of the DDS Draft (rather than in their order of perceived importance):

SECTION 2

We should first reiterate a point made at some length in our November 7, 2012 letter: that what is labeled Section 2 (previously denominated Phase I), does not offer the improvement(s) in supply chain security that are promised by California's pedigree law, and/or by the kind of national end-to-end track-and-trace/pedigree infrastructure in an interoperable format envisioned by the FDA in public comments it has made about its standards development under FDAAA. Although the DDS Draft studiously avoids use of the term "pedigree," what it contemplates in Section 2 is lot-level tracking of product through association of such product at the lot level with paper or electronic "pedigree" materials ("transaction history" and "transaction statement" documents). This is only a very small advance in security.

[2] Again, these comments are not intended to be exhaustive or comprehensive, and the failure to make a comment on any of the concepts and provisions in the DDS Draft is not intended to signal the Board's assent or lack of objection

While it includes a requirement of product (package) serialization, Section 2 does not require or provide opportunity for trading partners to do real-time, contemporaneous product validation (at the unit level, or even the lot level). Therefore, it does not provide substantial additional security, and does not materially advance us toward the universal track-and-trace infrastructure that is the endpoint. Moreover, these requirements seem to assume there will be identifications/interdictions of "suspect" / "illegitimate" drug products. However, it is not clear how, under this proposal, it would be *any more likely* that such products would be identified *before* an unfortunate patient-harm incident or other proof of illegitimacy. Given this unlikelihood, the notification/verification terms may be merely window dressing.

Section 581. Definitions

"Disposition" (§ 581(3)): We believe this concept needs further refinement, either in its definition or in its operational deployment throughout the draft. Specifically, we are concerned that the instructions throughout the draft for trading partners to "disposition" suspect/illegitimate product may be (or may be interpreted to be) an instruction to the investigating party to destroy/send for destruction suspect/illegitimate product without retaining a sample, *hampering the ability of investigatory agencies to study the suspect/illegitimate product, collect samples thereof, etc.* We believe some work may be required to specify that regulatory agencies must be offered (a sample of) suspect/illegitimate product for analysis and investigation before the product is shipped away or destroyed. We are also unsure whether the draft defines specifically enough who may make a "disposition" decision.

"Illegitimate Product" (§ 581(5)): Especially given how much hinges on these definitions (both this one and that for "Suspect Product," see below), we believe this term is (still) defined too narrowly. There are numerous additional types of illegitimacy that are not mentioned here, and that may not fit within the categories that are mentioned here, including subpotent/superpotent drugs, mislabeled or misbranded drugs, new drugs without appropriate approval(s), among others. We believe this should be given as broad a definition as possible. For this reason, we would also not limit it to "intentionally" adulterated product, as intention should be irrelevant if a drug is adulterated. Likewise, we would not make the definition of "illegitimate product" dependent on proof of either actual or potential patient harm, so we would remove the phrases starting with "such that . . ." from both (B) and (D). If this is not possible, we would at least change the "would" in sub-part (B) to match the "could" in sub-part (D).

"Suspect Product" (§ 581(17)): See comments for "Illegitimate Product," except that the definition for "suspect" product should be even more broad and inclusive, since this is merely the threshold for commencing an investigation (and potentially "clearing" the product). At a minimum, the "would" that appears in sub-parts (B) and (D) should in both instances be replaced with "could." But we believe that this definition should be significantly expanded, to include the numerous other possibilities that exist with regard to product interference, mislabeling, other otherwise illegitimate practices.

"Third-Party Logistics Provider" (§ 581(18)): We are not aware that 3PLs perform these services for (other) wholesalers, dispensers, or providers, and can think of no circumstances under which they might legitimately do so. We suggest this definition be further refined.

"Transaction" (§ 581(20)): Based on our experience with implementation of our law, we ask the working group to consider not limiting the transaction history to transactions in which a change of ownership occurs. In other words, we suggest you at least consider tracking every change of location and/or possession, since that will provide a more complete record and will be tracked (internally) by the trading partners, anyway. We are also concerned that this definition may introduce an inconsistency or ambiguity into the legislation, because the law also applies requirements to "transactions" not involving a change of ownership (e.g., transfers of possession to a third-party logistics provider).

We are also concerned about the exemption (in (B)(vii)) for distribution of a "minimal" quantity of products from a pharmacy to a practitioner for office use. This strikes us as an exemption that is ripe for widespread abuse, especially given our recent experiences with pharmacy re-sales and compounding.

"Transaction History" (§ 581(20)): We are perplexed by the continued allowance for a "paper" transaction history, as such paper documents can be easily forged or created post-hoc. Moreover, we ought to be developing the electronic infrastructure for real-time validation.

"Transaction Statement" (§ 581(23)): Similarly, we cannot understand why this would be a paper document. We would suggest that this (hopefully electronic) data have to be signed, and that it include an attestation by a party able to bind the entity (with an electronic or digital signature). What is not clear from this definition is whether this "transaction statement" will include *any* reference to quantity, lot number, number of containers, NDC numbers, SNIs, or any other identifying information for the particular drugs (packages, cases, lots, etc.) that are shipped and received. It does not appear there will be any requirement that the shipper or receiver make any attestation about the actual product. We think this is a mistake, and would substantially increase the requirements for this statement.

Section 582. Requirements[4]

Subdivision (a)(2)(A) (page 18): We believe that the word "draft" should be deleted.

Subdivision (a)(7) (page 22): We are confused by this provision, which appears to deem third-party logistics providers licensed without benefit of either State or Federal licensure proceedings. We believe that states should continue to license these entities, exercising their usual discretion.

Subdivision (b)(4)(B)(i)(II) (page 27): We believe that there needs to be a specification that, as part of the "disposition" of illegitimate product, each entity in possession or control of same (so this is a comment that will apply to succeeding sections of the draft, but will not be repeated) must offer the drug or a sample thereof to the FDA and/or state authorities, to retain for future investigation. Because there is no explicit requirement that a "disposition" include retaining the drug or a sample thereof, we are very concerned that we will lose the ability to conduct forensic analysis on these drugs for origin, etc.

Subdivision (b)(4)(B)(ii) (page 28): We do not believe that the requirement to notify regulatory bodies and trading partners of the existence of an illegitimate product should be contingent on an entity (here, manufacturer, but this comment also applies to the other supply chain partners) having possession or control of the product. Any trading partner having knowledge (or reason to know) of an illegitimate product should be obligated to share that knowledge (or suspicion) with the FDA and its partners.

Subdivision (c)(1)(A)(ii)(II) (page 34): We are confused and concerned by the exemption of the lot number, transaction date, and initial shipment date from the transaction history/information.

Subdivision (c)(1)(B)(i)(I) (page 37): Here and elsewhere in the draft, we are confused and concerned by the exemption from the requirement of provision and receipt of a transaction history for saleable returns. We believe that this exemption will simply invite waste and abuse.

Subdivision (d)(4)(C) (page 52): We believe that dispensers should have the same continuing obligation to respond to verification requests, notwithstanding maintenance of an electronic database, as do all other supply chain partners. Indeed, we believe that dispensers are of primary importance in the effort to ensure supply chain security, and we would like to see their role expanded, not diminished.

Subdivision (g) (page 65): We find this definition or deployment of drop shipments confusing and concerning, as under the heading of "drop shipment" this provision seems to exempt from all of the transaction statement/history, verification, and other requirements, any entity that does not physically handle a product. This is a significant broadening of the "drop shipment" concept with potentially real consequences that are as yet unknown, because this does not limit "drop shipment" to manufacturer-to-dispenser/administerer direct shipments. Moreover, as we know, many such entities take ownership of drug products, and so would (normally) be included in the "transaction" history of such products. This broad and general exemption will have an uncertain impact on the operation of the requirements.

SECTION 3

We would like to first express our appreciation for the increased level of certainty that is now inherent in Section 3, and the self-executing nature of its requirements. It is solely on this basis that we are able to offer our reserved support or lack of opposition to the DDS Draft.

However, we believe that Section 3 should be made effective far more quickly than 10 years from enactment. We would suggest a maximum period to effectiveness of 5-7 years. We know that a great deal of work has already been done to achieve compliance with California's pedigree law; we believe that work should not be rendered stale, and that momentum should not be lost, by this delay.

We also believe that Section 3 can and should be made still more certain, definite, and detailed, and should capitalize on the work that has already been done by the FDA to identify and define some or all of the requirements for an interoperable unit-level track-and-trace system. We do not believe further development or implementation of such requirements should be delayed or left to the future.

Finally, we believe that any such system should incorporate automatic verification (at unit level) by each supply chain trading partner, i.e., validation of shipped and received product against "pedigree" (transaction) data that is received and transmitted by supply chain trading partners. It is not clear to our eyes whether Section 3 requires this kind of routine verification (and associated attestation), and we do not believe any system that does not make that sort of automatic verification explicit is adequate. It is *not* sufficient for each trading partner to simply share the data pertaining to each single transaction with that trading partner, as this does not enable the kind of supply-chain visibility that is necessary for the (particularly downstream) trading partners to be assured of the legitimacy of the drug product(s).

Subdivision (a)(4) (page 71): We do not believe that the statute contemplates or requires the promulgation of regulations (at least with regard to system requirements), so do not understand this provision's reference to promulgation of such regulations. Should this read "guidance"?

Subdivision (l) (pages 83-84): We are confused and concerned by these sunset provisions, particularly that in subdivision (l)(1) calling for the sunset of exchanges of transaction histories.

SECTION 4

We are pleased to see that our concerns and recommendations regarding national licensure standards for wholesalers (and third-party logistics providers) were heard and considered, and that the result is what we understand to be legislation setting a floor but not a ceiling for license requirements. If we are in any respect mistaken about that understanding, we hope that can be clarified. But assuming we are not, we fully support the notion and execution of minimum national licensure standards. We would appreciate an explicit acknowledgment that states may enact additional/further requirements.

Subdivision (b) (page 88): We are, however, concerned by the inclusion of a list of exemptions from the definition of "wholesale distribution" that seems in many respects to mimic the similar list of exemptions from the definition transactions to be recorded on a transaction history. We do not see the utility of inclusion of this list. Some of the transactions in this list would not, in any event, constitute wholesale distributions, but some might, and there seems to be no reason to exclude those. More to the point, it seems to be better policy to adequately define "wholesale distribution," rather than burden this definition with a long list of excluded transactions that seems to be imported from elsewhere.

We also have particular concerns about some of the exclusions listed here, including sub-parts (E), (K), and (M) through (S). There seems no good reason to exempt these from the definition.

Section 583. National Licensure Standards for Wholesale Distributors

As referenced above, we would be more reassured if, somewhere in these provisions (on or about page 96 would seem to be the appropriate place), there were an explicit acknowledgment/allowance of states' continuing ability to enact and enforce requirements additional to the minimum federal standards.

SECTION 5

We continue to believe that third-party logistics providers can continue to be licensed/regulated as wholesale distributors, but recognize that reasonable minds can differ on this point and are willing to accede to your considered wisdom that they should be a separate license category. Our understanding of the federal statutory scheme is that this will require additional legislation in California and other states to create (and define) this separate license category. Again, we would hope that the federal legislation will retract its apparent intention to "deem" third-party logistics providers licensed, and make that dependent (as the draft elsewhere seems to do) on state and/or federal license approval.

Otherwise, we repeat our comment made above about wholesale distributor licensure, and ask for an explicit acknowledgment/allowance for enactment of state standards above the federal minimum.

SECTION 7

Subdivision (b) (page 105): This may be another, or the best, place to specify that states retain their present ability to enact licensing and enforcement requirements for wholesalers and third-party logistics providers that are above and/or additional to the federal minimum standards.

Conclusion

For all of these reasons, we offer our reserved support or lack of opposition to the proposal's direction, although we believe and reiterate that it can be made far stronger, and definitely should be implemented far more quickly. 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.

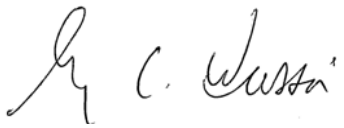
We also believe that the endpoint should be a national end-to-end track-and-trace system that is worthy of any additional delay, and adequate to replace the California model. We believe the necessary components of any such system include: participation by *all* industry partners; in passing and receiving 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.

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

Enclosure: November 7, 2012 Board comment letter