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

May 9, 2012

Representative Henry Waxman
2204 Rayburn House Office Building
Washington, DC 20515

RE: SECURING PHARMACEUTICAL DISTRIBUTION INTEGRITY
Comments of the California State Board of Pharmacy
H.R. 3026 – Safeguarding America's Pharmaceuticals Act of 2011
Securing Pharmaceutical Distribution Integrity Act of 2012 (Senate)

Dear Representative Waxman:

I write on behalf of the California State Board of Pharmacy (Board). We are pleased to have this opportunity to share with you our comments and concerns regarding the development of federal legislation addressing the security of the pharmaceutical distribution supply chain, a topic of considerable interest to this Board. We understand that this legislation is or may soon be included in bills relating to the Prescription Drug User Fee Act (PDUFA) reauthorization that are in motion in the Senate and/or the House of Representatives. We hope that you will consider our comments as you are asked to review, sponsor, or vote on legislation that addresses this topic.

We would first like to thank you for your historical and continued leadership on the topic of pharmaceutical supply chain security, and for your ongoing effort to solicit Board input on the path forward. We appreciate the regular contacts your staff have made with Board staff, and are pleased to have a partner at the federal level who is so supportive of California's pedigree law(s).

We support the idea of a federal approach. It would be best for supply chain security to be addressed at the federal level by a bill approximating the principles of the California law(s), given the scope of the regulated market. California stepped into this area of regulation out of a perceived need, in the absence of federal standard(s) and in response to acts of counterfeiting and other threats to security that led to the formation of the U.S. FDA Counterfeit Drug Task Force in 2003. But we acknowledge that a federal standard and enforcement would be advantageous. However, we also share your view, expressed during a May 1, 2008 hearing on H.R. 5839, that "federal legislation that seeks to nullify California's law must provide the same or greater degree of protection, or else preserve California's ability to proceed with its legislation."

We believe that H.R. 3026, the "Safeguarding America's Pharmaceuticals Act of 2011," as introduced on September 22, 2011, has the potential to establish this kind of robust federal standard. However, we do not believe the same can be said of another proposal under review, known variously as the "Pharmaceutical Traceability Enhancement Code (RxTEC) Act" or the "Securing Pharmaceutical Distribution Integrity Act of 2012." We are writing to express our concerns about this legislation, that would preempt California's law and replace it with what we believe is a less robust, and less secure, supply chain infrastructure.

History and Structure of California's Pedigree Law(s)

As you know, California and this Board have taken a leading role in setting standards for securing the prescription drug supply through deployment of our pedigree law(s). Inspired in part by a vision of a universal electronic pedigree/track-and-trace infrastructure laid out in FDA Counterfeit Drug Task Force reports in 2003, 2004, 2005, and 2006, between 2003 and 2008 the Board worked with the California Legislature to enact and amend California law(s) requiring adoption of such an infrastructure. The most recent amendments to the law(s), in 2008, were the outcome of careful and protracted legislative negotiations involving many stakeholders. Our legislative record includes statements of support from many of the most important players in all segments of the industry, reflecting a rough consensus that the California approach is the best way forward. As you are aware, the basic elements of the California approach call for staggered implementation between 2015 and 2017 of a pedigree/track-and-trace infrastructure including:

- An electronic pedigree record showing each change in ownership, from original manufacturer (and/or subsequent repackager), through all drug distributor(s), to final dispenser/furnisher/administerer(s) of the dangerous drug;
- Data that is exchanged in an interoperable electronic system incorporating track and trace infrastructure, based on a unique identifier established at point of manufacture;
- Tracking at the smallest package or immediate container (saleable unit); and
- Data that is passed, certified, and authenticated by all supply chain participants.

In our view, deployment of such an infrastructure promises significant benefits. It was originally designed to prevent or diminish introduction of counterfeit, misbranded, or adulterated drugs into the secure supply chain. It clearly serves this purpose, while also providing tools for investigation and enforcement of any such intrusions, promoting accountability. As has recently been shown by the Avastin example,[1] pharmaceutical counterfeiting remains a real and perhaps growing threat to the security of our drug supply.[2] As does drug diversion and black market sale of pharmaceuticals, as illustrated by the indictment recently announced by New York Attorney General Schneiderman of a ring distributing black market/diverted HIV medications.[3]

A universal electronic pedigree/track-and-trace infrastructure also has great potential to address other significant threats to our drug supply. For instance, our experience in California with the Heparin recall(s) in 2008,[4] and with more recent drug and device recalls, has convinced us there are gaps and deficiencies in our nation's current recall practices. Problems include the sheer number of recalls initiated each year, resulting confusion over whether any recall notice that is received is new or duplicate information, and confusion and debate over the "voluntary" nature of most recalls. As the Heparin example demonstrated, it is unlikely that most recalls result in the desired effect of removing all doses of a drug from the market. Universal electronic pedigree/track-and-trace infrastructure could vastly improve the operation, specificity, reliability and accountability of recall processes. Recalls could be targeted, and their accuracy tracked.

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[1] See "Counterfeit Version of Avastin in U.S. Distribution," Statement by the FDA, February 14, 2012, available at http://www.fda.gov/Drugs/DrugSafety/ucm291960.htm.

[2] See also, e.g., Dr. Sanjay Gupta's report on counterfeit prescription drugs for "60 Minutes," aired March 13, 2011.

[3] See Press Release, April 4, 2012, available at http://www.ag.ny.gov/press-release/ag-schneiderman-announces-arrests-274-million-black-market-prescription-drug-operation.

[4] See, e.g., "Information on Heparin" in Postmarket Drug Safety Information for Patients and Providers, available at http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM112597.

Likewise, the historical problem of "shrinkage" and loss of inventory control via theft and/or diversion seems to be growing dramatically in scale, as more and more drugs disappear on a daily basis for resale and/or are taken in large cargo thefts or warehouse burglaries.[5] There is very likely growing involvement by organized crime in theft and resale of pharmaceuticals. The obvious motivators include lesser exposure to criminal penalties and a ready market for resale of those drugs into the supply chain. A universal electronic pedigree/track-and-trace infrastructure could significantly diminish if not eliminate the market for stolen and diverted products, since a stolen or diverted drug would not have the requisite electronic documentation for such resale.

The Board and its staff have several years' experience developing and then implementing pedigree laws. Further, since 2005 the Board and its staff have engaged in extensive outreach to all segments of the drug supply chain on the California pedigree law, including hosting regular public meetings and workgroups, conducting private meetings with members of all segments of the industry, attending industry conferences, publishing Question and Answer documents on the law and its implementation, and other similar efforts. We have been repeatedly assured through that process that the California pedigree approach to drug security is the "gold standard" among the various approaches outlined to date, either at the federal level or by the various states.

That "gold standard" consists of several basic elements and requirements that make the California drug pedigree law a uniquely comprehensive approach to prescription drug security. The elements of the law that we consider crucial to its purpose include the following:

- The requirement of a "pedigree" record for every prescription drug, initiated by every manufacturer and transmitted and appended through the supply chain, with required data regarding each transaction resulting in a change of ownership of every drug – to be fully effective, we believe the pedigree requirement must be universally applied;
- The record must be created, transferred/received, and maintained, in an electronic form, using secure electronic transactions to enhance the security of the data – in our experience, paper pedigrees are more easily counterfeited and duplicated;
- The pedigree tracks each drug down to its smallest saleable unit, e.g., each bottle in a case of 48 bottles – the only way to effectively track and prevent counterfeits or drug adulteration is by a system that requires individual-unit mass serialization;
- The pedigree uses and is based on a unique identification number affixed to smallest unit packages by the manufacturer, and is created/maintained within an interoperable electronic system using a standardized nonproprietary data format and architecture – reliance on standards and nonproprietary formats discourages data segmentation;
- One pedigree record tracks all changes of ownership of a given prescription drug in a supply chain, including lateral transfers (e.g., wholesaler to wholesaler), downstream transfers (e.g., manufacturer to wholesaler), and upstream transfers (e.g., pharmacy to wholesaler, including returns and recalls) – without one universal record as to all such transactions, there is no reliable audit trail to source counterfeits or adulterations; and
- The pedigree must contain certifications of delivery and receipt, and a certification of the authenticity of the pedigree data from each source/owner of the drug – this assists with traceability, auditability, and accountability of the pedigree record.

[5] See, e.g., Katherine Eban, "Drug Theft Goes Big," *Fortune*, March 31, 2011.

In large part, these basic elements arise from and are consistent with the recommendations of the FDA Counterfeit Drug Task Force, first convened by then-FDA Commissioner Mark McClellan in July 2003. In its 2004 Report, the Task Force recommended industry adoption of RFID as the standard track and trace technology, to be used for mass serialization/unique identification (at the unit level) of all drugs in or by 2007, and further recommended industry implementation of a full electronic track and trace/pedigree system by the same date. (2004 Report, pp. 9-15.) In its most recent (2006) Report, the Task Force again noted the desirability and feasibility of a universal e-pedigree system based on package-level RFID serialization, and expressed disappointment that it would not be achieved by 2007. (2006 Report, pp. 7-17). The 2006 Report reinforced the utility of package-level identifiers and tracking (pp. 12-14), and of a universal and uniform requirement that all participants in the distribution chain be required to send or receive pedigrees (pp. 14-16). That Report specifically singled out California as having advanced the pedigree cause (p. 9).

This mention of California in the 2006 Report mirrors a level of support that California has received from the FDA for its law since its enactment, particularly over the last several years, wherein the FDA has repeatedly testified at Board hearings in support of the California law. The Board of Pharmacy has been grateful for this support, and remains very engaged with the FDA.

Because of California's size and share of the market for prescription drugs, the California model for a universal electronic pedigree/track-and-trace infrastructure has been driving industry action for the last several years. All segments of the supply chain appear to be actively preparing for the negotiated 2015-2017 deadlines in California law. We believe in that model, and will be ready to enforce its provisions should it become necessary to do so. We are excited about what it will mean for the supply chain to have full compliance with the infrastructure requirements. We fully expect a more dynamic, secure, and accountable supply chain to be the result.

Pending Federal Legislation

We also know, however, that to be most effective the universal electronic pedigree/track-and-trace infrastructure ought to be deployed and enforced at the federal level.[6] We are therefore pleased to see that the FDA is making real strides toward this goal. The Final Guidance issued in March 2010 defining the Standardized Numerical Identifier (SNI) that the FDA recommends for serializing drug products in a pedigree/track-and-trace infrastructure is an excellent document, by all reports the result of an industry consensus on this standard.[7] And it is clear that the FDA has made substantial progress toward defining its preferred "System Attributes" for track-and-trace infrastructure requirements since convening a public workshop on this subject in February 2011.[8]

We are especially pleased to see so many commonalities between the California law and the "System Attributes" distributed by the FDA for discussion at the public workshop, and made public in various fora (including Board meetings) since. We hope that the FDA, and legislation that may result at the federal level in consultation with the Board and the FDA, will continue to look to California for an effective model, one for which the industry is now actively preparing.

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[6] The 2008 amendment(s) to the California pedigree law(s) also contemplated federal action in this arena, providing that any enactment of federal statutes or regulations addressing pedigree or serialization of drugs would render the California law(s) inoperative, and that any provision inconsistent with subsequent FDA rulemaking is likewise void. In other words, California law contains "self-preemption" provisions, even if any eventual federal law does not.

[7] The Board has taken initial steps to make clear that the SNI should be used for serialization under California's law.

[8] The Board, through its Executive Officer, was a primary participant in the public workshop in February 2011.

Unfortunately, we feel that the legislative proposal now circulating at the federal level, known variously as the "Pharmaceutical Traceability Enhancement Code (RxTEC) Act" or the "Securing Pharmaceutical Distribution Integrity Act of 2012" (and perhaps also by other names), is not an effective equivalent to the California pedigree law(s). Rather, by its own terms as well as by the operation of the "self-preemption" language in the California law, this proposal would preempt the California pedigree requirements, and replace them with a less robust and ultimately less purposeful federal infrastructure. Therefore, while we are excited to see some action on this subject at the federal level, and while we recognize that in some small ways this proposal makes improvements in existing federal law,[9] we are writing to convey our concern that this legislation, if enacted as proposed, would provide less immediate supply chain security than California law.

As we understand the various versions of that proposal,[10] our primary concerns relate to the following features of the "RxTEC System" that it envisions creating:[11]

- **Timing:** The proposal calls for various implementation dates triggered by issuance of final regulations by the Secretary. Even assuming those regulations are issued by the 18-month deadline set forth in the proposal, the "RxTEC System" would not be fully rolled out (i.e., require participation by dispensers) until 6 years after that date. So the earliest date for full implementation would be sometime in 2020, a full three years after the final implementation date of the California law. And given the failure to fully promulgate or implement regulations required under the Prescription Drug Marketing Act (PDMA) in the nearly 25 years since its enactment, it is not difficult to imagine that federal implementation of this law would likewise be further delayed.

- **Non-Utilization of Serialized Numeric Identifiers:** Although the proposal calls for manufacturers (and repackagers) to apply "RxTEC" data carriers that include the SNI to individual saleable units and homogeneous cases, it frankly does not require much to be done with those data carriers or the associated data. For one thing, the proposal requires that tracking routinely take place only at the lot level (a lot could include up to hundreds of thousands of individual units). It is not clear what purpose is served by using an RxTEC data carrier to track at the lot level, since this would be entirely duplicative of the (human-readable) lot numbers that are already printed on individual units. The proposal envisions a significant investment to affix serialized identifiers to individual units and cases without any clear purpose for doing so. And even within this apparent requirement to affix numeric identifiers, there is significant ambiguity, since the proposal also seems to provide numerous exemptions to this requirement in the "Limitations" subdivision that would appear to be transaction-specific (e.g., sales in an emergency), but which arguably provide a broad exemption to all requirements.

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[9] For instance, we acknowledge that this would be the first federal requirement to serialize drug products at the unit level, though as our subsequent comments make clear too little is being done by supply chain participants with those serial numbers to ensure supply chain security. Similarly, we recognize that the proposal(s) aim to tighten up/ make more uniform 3PL, wholesaler, and manufacturer licensing requirements (by states), but again, because California is already a leader in these requirements, in some ways these provisions would actually relax California standards. We do welcome the proposal's efforts to rein in online pharmacies, and to increase the penalties for drug counterfeiting.

[10] Because several drafts of the proposal have circulated, and additional changes may have been made since the latest copy was shared with us, we will not attempt to tie our comments to particular sections or provisions of the proposal but will instead offer general comments on provisions that appear to be in common among the various drafts or that seem to have been retained in the latest versions of the proposal that were shared with Board staff.

[11] We have not attempted to be comprehensive in our comments, and are limiting ourselves to our primary concerns.

- **Specification of 2D Barcode Technology:** The RxTEC proposal also specifies the use of 2D data matrix barcodes as standard data carriers. California has assiduously avoided specification of carrier technology, although at the time its law was originally enacted the author of the bill assumed, as did the FDA, that this data would be coded and read using RFID tags. California has preferred to let the market dictate the means of data transmission, and has sought to avoid interfering with technology innovations that may be developed to respond to the outcomes dictated by California law. While it is true that to this point 2D data matrix barcodes appear (based primarily on cost) to be the preferred carrier being employed by the industry participants who are readying for California compliance, there is still the chance that a further drop in price of RFID technology, or development of some other technology, will result in adoption of some other form of data carrier in addition to or as an alternative to 2D barcodes. There are some obvious disadvantages to 2D barcodes, including most notably that 2D barcodes require line-of-sight scanning (which RFID tags do not). We are hesitant to "freeze" innovation by specifying 2D data matrix barcodes as the default data carriers, even if the Secretary is given latitude to allow other data carrier technologies as supplements. It is difficult to imagine supply chain participants, where the default under the law is a 2D data matrix barcode, ever investing in any other data carrier technologies.

- **Lack of Verification/Validation of Product and Data:** As the FDA has repeatedly expressed, the best way to interdict and prevent counterfeits and other sub-standard drugs from reaching patients is to create a "closed system" within which every drug product is tied to a data infrastructure (by its SNI), and is scanned at each point in the distribution chain so that if a product *does not have* a valid SNI, it can be immediately quarantined and its origins investigated. The RxTEC proposal does not envision this kind of universal verification/validation of drug products to the data that is required under California law to accompany physical transfer of the drugs. In fact, the RxTEC proposal does not appear to require that the SNI data carriers will *ever* be scanned by wholesalers, pharmacies, or other downstream participants in the supply chain, and certainly does not envision that any supply chain participants will ever validate the drug product that is received. Again, under these circumstances it is not clear what purpose would be served by affixing an RxTEC data carrier, where the data carrier will never be read. As a practical matter, the RxTEC proposal does not enhance the ability of supply chain participants to *automatically detect and intercept* counterfeits or other suspect products; they will not scan that product and detect anything about its SNI or other identifiers that is suspicious. Under California law, a counterfeiter will have to steal or fabricate enough SNIs to be able to label counterfeit product, but then that product should be intercepted almost immediately, because the illegitimate SNIs would be read by the first buyer and compared to SNIs authorized by the legitimate manufacturer. By contrast, under the RxTEC proposal, there is no opportunity to intercept illegitimate SNIs (assuming the counterfeiter even bothered to apply SNIs).

- **Practical Inability to Investigate/Trace "Suspect Product":** Along the same lines, although the RxTEC proposal says that the Secretary or a state could require one-up, one-down investigation of "suspect product," without an infrastructure within which a product is being scanned and tracked at each level of distribution, this is not possible to do at the unit level. All investigations and recalls will remain at the lot level.

- **Broad Exemptions from Participation:** As mentioned above, even the reach of the "RxTEC System" requirements is called into significant question by the inclusion of a laundry list of exemptions in the "Limitations" section of the proposal. Particularly curious about many of these exemptions is that while they appear to describe specific *types* of transactions (e.g., intracompany sales, group purchasing transfers, charitable sales, emergency sales, transfers pursuant to mergers, etc.), the exemptions granted to these transactions relate to the entire chapter, and are not transaction-specific. So for a given transaction (e.g., an intracompany sale), it is not clear at what point in time an exemption would be applied. Would any drug product that is ever transferred within a company or a purchasing group be forever exempted from the requirements of this chapter? This is how this list of exemptions appears to read. If so, these exemptions are so broad as to render the legislation's requirements effectively meaningless.

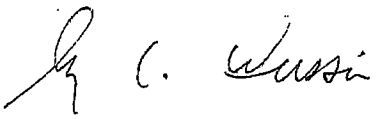
- **Prohibition on Aggregation:** We also believe that an infrastructure that intends to track drug products at the unit level within an industry that distributes these units in a non-regular aggregate format (e.g., homogeneous and non-homogeneous totes, cases, pallets, etc.), especially one that depends on a non-line-of-sight technology such as a 2D data matrix barcode, must rely on aggregation of product and product data into a hierarchical data structure. For instance, the only way to track individual units within an aggregation (such as a case or pallet), without having to open every case or pallet and individually scan its contents, is to have the individual SNIs for those drug units associated with another data point (e.g., a case or pallet SNI). There are legitimate questions to be explored about whether it is appropriate to *infer* from a "good read" on a case or pallet identifier that the expected contents of that aggregate container are contained within, but it is difficult to imagine a serious data sharing infrastructure for tracking and tracing drug products that does not make at least some use of aggregate structures and data identifiers. Yet the RxTEC proposal not only does not require or encourage aggregation, it specifically prohibits the regulations from doing so. This seems to signal that there is no intention to ever track products at the unit level.

- **Restrictions on State Enforcement:** And finally, we are concerned that if our own law(s) are preempted by the RxTEC proposal, California's enforcement capacities as to investigations of counterfeits or other suspect products will likely be significantly curtailed. First, the proposal contemplates that even the FDA will only be authorized to "request" RxTEC data from supply chain participants in the event of a recall or as necessary to investigate "suspect product." But this allowance for investigation of a "suspect product" appears to be circular, since it is not clear how "suspect product" is ever likely to be identified in the absence of FDA (or state) inspection of same, where the supply chain is not routinely validating that product. Also, as mentioned above, it is not clear what data could possibly be transmitted by the supply chain in aid to any such investigation. Second, even this limited authority given to the FDA is available to the states only upon specific delegation from the Secretary. So whereas the Board is now authorized under California law to inspect California wholesalers/pharmacies, and could review maintenance of pedigree data, implementation of the pedigree law, and receipt of serialized, pedigreed drug products as part of its routine inspections, it would not appear to have that same ability if this proposal becomes federal law.

For all of these reasons, we are concerned about the impacts that the RxTEC proposal is likely to have on the security of the supply chain in California, and by extension in the rest of the country, by replacing California's pedigree law with a less robust infrastructure. While we agree in principle that a uniform national standard would be ideal, we would like to see that standard a much closer approximation of the California model than is reflected in the RxTEC proposal. We would encourage something closer to the Bilbray-Matheson model of H.R. 3026. We once again commend you for your leadership on these vital issues of national drug security.

Thank you for your attention to these matters, and for your willingness to hear our input. We look forward to continuing to work together to secure the nation's drug supply. Please feel free to contact the Board at 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.

Sincerely,



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