THE REPUBLICAN STUDY COMMITTEE
Rep. Steve Scalise, Chairman
Paul Teller, Executive Director
202.226.9717
rsc.scalise.house.gov

Legislative Bulletin……June 3, 2013

Contents:

H.R. 1919 – Safeguarding America's Pharmaceuticals Act of 2013, as amended (Latta, R-OH)

Order of Business: H.R. 1919 is scheduled to be considered on Monday, June 3, 2013, under a motion to suspend the rules and pass the bill requiring a two-thirds majority vote for passage.

Summary: H.R. 1919 amends the Federal Food, Drug, and Cosmetic Act[1] to manage the integrity and security of the nation's prescription drug supply chain to thwart counterfeit or adulterated drugs from entering the supply chain and being dispensed to patients. The bill creates a national tracking and tracing standard that applies to all entities involved in the pharmaceutical distribution supply chain including prescription drug manufacturers, third-party logistics providers (TPLs), wholesalers, repackagers (i.e., secondary wholesalers), and ultimately, dispensers, such as pharmacies or hospitals.

Highlights of the major provisions of the bill are included below:

- Beginning on January 1, 2015, and including future phase-in dates, the transaction history and statement of a change of ownership for lot-level prescriptions are required by all entities and must be maintained for three years. The Secretary of Health and Human Services (HHS) must establish applicable standards by regulation within 180 days in conformity with widely recognized international standards and a waiver process for entities that experience undue economic hardship or emergency medical reasons;
- Manufacturers must develop a serialization process for all prescription drugs at the unit-level (individual prescriptions) within five years after enactment;

[1] 21 U.S.C. 351 et seq.

- By January 1, 2027, the U.S. Food and Drug Administration (FDA) is required to issue a proposed regulation for tracing the unit-level of all domestic prescription drugs dispensed to patients;
- Requires that supply chain entities only transact with registered or licensed entities;
- Imposes FDA notification and response requirements on drug supply chain entities upon the presence or determination of suspect or illegitimate prescription drug products;
- Requires the HHS Secretary, in consultation with industry stakeholders, to establish a pilot project within two years of enactment to explore and evaluate methods to enhance the safety and security of the pharmaceutical distribution supply chain. It also requires the HHS Secretary to host bi-annual public meetings to address best practices, the costs and benefits of the bill's goals, impact on small businesses, etc;
- Provides the HHS Secretary the authority to provide for alternative small business methods of compliance for requirements established in the bill if any requirements would result in an undue economic hardship upon small businesses;
- Requires the HHS Secretary to establish national standards for the licensing of prescription drug wholesale distributors that include the storing and handing of drugs, maintenance of drug records, financial bonding, mandatory background checks of facility managers, key personnel qualifications, mandatory physical facility inspections, and the prohibition of certain persons from engaging in wholesale distribution. States retain their licensing authority and ability to collect licensing fees;
- Establishes a national third-party logistics provider licensure requirement if the state from which a drug is distributed does not have a state licensure program. This provision permits the FDA to charge user fees to third-party logistical providers;
- Creates penalties for violations of the bill's requirements as well as increased penalties for willful violations;
- Preempts upon enactment any state or local political subdivision law, requirements, or regulation pertaining to tracing drugs through the distribution system that are "inconsistent with, more stringent than, or in addition to any requirement applicable under this Act…" or wholesale drug distributor or third-party logistics provider licensure which are "inconsistent with, less stringent than, in addition to, or more stringent than, the standards and requirements under this Act";
- Permits electronic prescription drug labeling (other than container or container labels) to be provided to physician, pharmacists, or other health care professionals; and
- Exempts certain prescription drug transactions from the bill's requirements that involve intercompany distributions, among hospitals or other health care entities under common control, for emergency medical reasons except for drug shortages not caused by a public health emergency, by a charitable organization to a non-profit affiliate of the organization, or to or from any facility that is licensed by the Nuclear Regulatory Commission or by a State pursuant to an agreement with such Commission.

Additional Background: Reports indicate an increase in the prevalence of counterfeit or adulterated drugs entering the nation's prescription drug supply chain. H.R. 1919 seeks to address what many pharmaceutical entities believe is an appropriate resolution to this challenge: a national system for tracking and tracing the route prescription drugs take initially from manufacturer to ultimately the retail pharmacy or hospital dispenser.

In the past year, the FDA has issues three different warnings about counterfeit drugs, including some meant for cancer patients. An Institute for Medicine's report published earlier this year, at the request of the FDA, studied "approaches to mitigating the problems of substandard, falsified and counterfeit pharmaceuticals" while focusing "on the public health aspects of the problem." The report recommended that Congress adopt a national policy by authorizing and funding the FDA to establish a mandatory track and trace system and convene a working group of stakeholders from the pharmaceutical industry to promote voluntary track and trace for all supply chain actors in accordance with existing guidance.

A group of more than 25 prescription drug supply chain entities formed a trade association about a year and half ago called the Pharmaceutical Distribution Security Alliance (PDSA) committed to developing a national solution to protect patients and secure the U.S. drug distribution supply chain. These stakeholders that include biopharmaceutical manufacturers, distributors, wholesalers, pharmacies, and logistics providers coalesced together primarily to develop a track and trace alternative and address the compliance requirements and regulations individual states have been adopting. While almost half of the states have enacted some version of legislation or regulation requiring differing track and trace requirements, California's legislation scheduled to take effect in 2016 has been characterized as being most burdensome and costly to implement according to industry stakeholders.[2]

Some conservatives question whether a single, uniform and national supply chain structure that governs all components of the nation's prescription drug supply chain is consistent with our nation's federalism principles given that states have enacted similar laws and regulations. Supporters of the approach taken by H.R. 1919 maintain that a current "patch-work" of state laws allows bad actors to forum shop for less stringent state venues while increasing the regulatory burden through multiple state-by-state systems with little benefit to public health. Also, supporters explain that the problem H.R. 1919 seeks to address is consistent with the intent of the Constitution's Interstate Commerce Clause described in Article I, Sec. 8, Clause 3.

Committee Action: On May 8, 2013, the House Committee on Energy and Commerce Subcommittee on Health marked up a discussion draft of the bill. Representative Robert E. Latta (R-OH) then introduced H.R. 1919 on May 9, 2013. On May 15, 2013, the full Committee marked up the amended bill and reported it out favorably by voice vote.

Administration Position: No Statement of Administration Policy has been released.

Cost to Taxpayers: The Congressional Budget Office (CBO) released a cost estimate for the bill on May 31, 2013. It explains that implementing the bill would increase federal revenues by $19 million over the FY2015-FY2018 period ($24 million over the FY2015-FY2023 period) and have a discretionary cost of $39 million over the FY2014-FY2018 period assuming authorization of appropriations.

[2] Approximately 4 billion prescriptions are dispensed to patients in the US each year (approximately 500 million prescriptions dispensed in CA each year). Estimates show the compliance costs for California's law to be $3.5 billion for all pharmaceutical product lines.

Does the Bill Expand the Size and Scope of the Federal Government? The bill creates a national prescription drug system for monitoring the movement of prescription drugs through the drug distribution system. It also requires the FDA to establish a licensing program for third-party logistics providers as well as national standards for prescription drug wholesale distributors. Also, the bill preempts any state or local law related to the traceability of prescription drugs.

Does the Bill Contain Any New State-Government, Local-Government, or Private-Sector Mandates? The CBO report explains that the bill contains both new intergovernmental and private-sector mandates as defined in the Unfunded Mandates Reform Act (UMRA) by requiring public and private entities to comply with standards for monitoring the movement of prescription drugs through the distribution system. It estimates that the costs to public entities to comply with such mandates would be below the intergovernmental threshold established in UMRA but that the costs to private entities exceed the threshold established in UMRA ($150 million in 2013, adjusted annually for inflation).

Does the Bill Contain Earmarks/Limited Tax Benefits/Limited Tariff Benefits? No.

Constitutional Authority: The Constitutional Authority Statement accompanying the bill upon introduction states, "Congress has the power to enact this legislation pursuant to the following: Taxation: Article I, Section 8, Clause 3. The Congress shall have Power to regulate Commerce with foreign Nations, and among the several States, and with the Indian Tribes."

RSC Staff Contact: Joe Murray, Joe.Murray@mail.house.gov, (202) 226-0678

S. 622 – Animal Drug and Animal Generic Drug User Fee Reauthorization Act of 2013
(Harkin, D-IA)

Order of Business: S. 622 is scheduled to be considered on Monday, June 3, 2013, under a motion to suspend the rules and pass the bill requiring a two-thirds majority vote for passage.

Summary: S. 622 reauthorizes from FY2014-FY2018 two animal drug-related review programs administered by the U.S. Food and Drug Administration (FDA) that are scheduled to expire on September 30, 2013, the end of FY2013. The bill provides continued authority for the FDA to impose fees on both animal brand drug manufacturers and animal generic drug manufacturers in order to assist the FDA's review activities pertaining to the development and marketing approval of animal drugs. The fees include animal drug application fees, product fees, establishment fees, and drug sponsor fees, which can only be collected and made available for obligation to the extent and in the amounts provided in advance appropriation acts. The Congressional Budget Office (CBO) estimates the FDA will collect $114 million from animal brand drug

manufacturers[3] and $38 million from animal generic drug manufacturers[4] over the five year period. Spending by the FDA authorized in the bill is offset by the collection of these fees.

S. 622 makes several technical changes to the FDA's existing programs for both brand and generic animal drugs including requiring FDA consultations with expert stakeholders, consumer groups, and congressional committees of jurisdiction, and requiring the FDA to publish future recommendations of reauthorizations of these programs. Also, the bill requires the submission of annual FDA performance and fiscal status reports to Congress.

Additional Background: Congress initially enacted the Animal Drug User Fee Amendments in 2003 and the Animal Generic Drug User Fee Amendments in 2008 to assist the FDA in expediting the animal drug approval process, reduce application backlogs, and improve FDA communications with animal drug sponsors. These programs were modeled on the Prescription Drug User Fee Program for human drugs initially enacted in the early 1990's and reauthorized last year. S. 622 represents the second reauthorization of the animal brand drug program and the first reauthorization of the animal generic drug program. Current law prescribes a statutory process for the FDA and the animal drug industry to negotiate an agreement regarding the size and scope of the user fees before the FDA submits its legislative recommendations to the congressional committees of jurisdiction.

Committee Action: Senator Tom Harkin *(D-IA)* introduced S.622 on March 20, 2013. On May 8, 2013, the Senate passed the bill by unanimous consent. The House Committee on Energy and Commerce passed a nearly identical version (H.R. 1407) of S. 622 out of Committee by voice vote on May 15, 2013.

Administration Position: No Statement of Administration Policy has been released.

Cost to Taxpayers: CBO released a cost estimate for S.622 on May 20, 2013, estimating the bill would reduce discretionary spending by $7 million over the FY2014-FY2018 period, assuming authorizations of appropriations. The authorized spending will be offset by the collection of fees, but CBO estimates a net reduction of $7 million over the five-year period "mostly because the spending of authorized fees lags slightly behind their collection."

Does the Bill Expand the Size and Scope of the Federal Government? The bill extends for five years current-law authority for the FDA to collect industry fees to expedite animal drug development and the FDA marketing approval process scheduled to expire at the end of FY2013.

Does the Bill Contain Any New State-Government, Local-Government, or Private-Sector Mandates? CBO explains that the bill contains no intergovernmental mandates as defined in the Unfunded Mandates Reform Act (UMRA) and would impose no costs on state, local, or tribal governments. It also explains that the FDA imposition of fees on private entities would be considered a private-sector mandate as defined in UMRA, but that the amounts of fees collected

[3] The total breakdown of FDA fees collected from animal brand drug manufacturers includes 20 percent for application fees, 27 percent for product fees, 27 percent for sponsor fees, and 26 percent for establishment fees.
[4] The total breakdown of FDA fees collected from animal generic drug manufacturers includes 25 percent for application fees, 37.5 percent for product fees, and 37.5 percent for sponsor fees.

would not exceed the annual threshold specified in UMRA ($148 million in 2014, adjusted annually for inflation) in any of the five ears that the mandate would be effective.

Does the Bill Contain Earmarks/Limited Tax Benefits/Limited Tariff Benefits? No.

Constitutional Authority: S. 622 does not provide the constitutional authority to enact this legislation. However, the Constitutional Authority Statement accompanying the nearly identical bill (H.R. 1407) reported by the House Committee on Energy and Commerce states, "Congress has the power to enact this legislation pursuant to the following: Article I, Section 8, Clause 3: To regulate Commerce with foreign nations, and among the several States, and with the Indian Tribes."

RSC Staff Contact: Joe Murray, Joe.Murray@mail.house.gov, (202) 226-0678

H.R. 126 – Corolla Wild Horses Protection Act (Jones, R-NC)

Order of Business: The legislation is scheduled to be considered on June 3, 2013, under a motion to suspend the rules and pass the bill.

Summary: H.R. 126 would direct the Secretary of the Interior to enter into an agreement with the Corolla Wild Horse Fund to provide for the management of the free-roaming wild horses near the Currituck National Wildlife Refuge.

The agreement specifies that the Corolla Wild Horse Fund shall maintain the herd of wild horses between 110 and 130. The Fund is further directed to maintain the horses and ensure that the natural resources of the refuge are not adversely impacted. The Fund shall also introduce a "small number" of wild horses from the herd at Cape Lookout National Seashore in order to maintain the genetic viability of the herd within the Currituck National Wildlife Refuge. The legislation contains certain criteria for bringing a horse from Cape Lookout National Seashore for introduction at Currituck National Wildlife Refuge.

The Corolla Wild Horse Fund is responsible for the following costs associated with the agreement:

- "Coordinating a periodic census and inspecting the health of the horses;
- "Maintaining records of the horses living in the wild and in confinement;
- "Coordinating the removal and placement of horses and monitoring of any horses removed from the Currituck County Outer Banks; and
- "Administering a viable population control plan for the horses including auctions, adoptions, contraceptive fertility methods, and other viable options."

Additional Information: The Corolla Wild Horse Fund is a 501(c) 3 nonprofit corporation located in Corolla, North Carolina. More information can be found here.

The Currituck National Wildlife Refuge is located in the northern portion of Currituck Sound on an Outer Banks barrier island. The Refuge is overseen by the U.S. Fish & Wildlife Service. More information can be found here.

According to House Report 113-077:

> The Currituck National Wildlife Refuge was established in 1984 to manage waterfowl, migratory birds, and endangered species such as piping plovers and sea turtles. FWS will allow wild horses to freely roam the Refuge as long as the horses do not significantly impact habitat or wildlife. While FWS has been unable to quantify any negative impacts of the eight Corolla horses that utilize refuge land, FWS views the Corolla wild horses as an introduced feral animal.
>
> This legislation would require the Secretary of the Interior to enter into a new agreement with the CWHF, the County of Currituck, and the State of North Carolina within 180 days after the date of enactment. Under the terms of the new agreement, the size of the herd would be `not less than 110 and not more than 130 free-roaming wild horses.' It would also provide for the cost-effective management of the herd and the introduction of a small number of free-roaming wild horses from the herd at the Cape Lookout National Seashore. There is no cost to the federal government for the management of these horses and no authorization of appropriations. All expenses related to the wild horse management throughout their range have been and would continue to be paid by the CWHF.

Similar legislation, H.R. 306, passed the House of Representatives on February 6, 2012, by voice vote. The RSC's Legislative Bulletin for H.R. 306 can be found here.

Committee Action: H.R. 126 was introduced on January 3, 2013, and was referred to the Natural Resources Subcommittee on Fisheries, Wildlife, Oceans, and Insular Affairs. The full committee held a markup on April 24, 2013, and the legislation was favorably reported by unanimous consent.

Administration Position: No Statement of Administration Policy is available.

Cost to Taxpayers: CBO estimates that "the organization would manage the wild horse population using private funds; we estimate that the federal government would incur no significant additional costs to manage or mitigate the effects of horses on the refuge. If, however, CWHF was unable to maintain the population at or below 130 horses as required under the bill, CBO expects that USFWS would incur costs totaling roughly $200,000 a year to manage the horses." CBO's report can be found here.

Does the Bill Expand the Size and Scope of the Federal Government?: Yes. The legislation directs the Secretary of the Interior to enter into an agreement with the Corolla Wild Horse Fund.

Does the Bill Contain Any New State-Government, Local-Government, or Private-Sector Mandates?: CBO states that "H.R. 126 contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act and would impose no costs on state, local, or tribal governments."

Does the Bill Contains Earmarks/Limited Tax Benefits/Limited Tariff Benefits?: No.

Constitutional Authority: Rep. Jones' statement of constitutional authority states "Congress has the power to enact this legislation pursuant to the following: Article I, Section 8, and Article IV, Section 3, of the Constitution of the United States." The statement can be viewed here.

RSC Staff Contact: Curtis Rhyne, Curtis.Rhyne@mail.house.gov, (202) 226-8576.

H.R. 1206 - Permanent Electronic Duck Stamp Act of 2011 (Wittman, R-VA)

Order of Business: The bill is scheduled to be considered on June 3, 2013, under a motion to suspend the rules and pass the legislation.

Summary: H.R. 1206 would allow the Secretary of the Interior (through the U.S. Fish and Wildlife Service) to authorize any state to issue electronic duck stamps. These stamps are necessary in order to hunt migratory waterfowl. The legislation contains criteria to be included in a state's application to the Secretary in order to issue electronic stamps.

These stamps shall be valid for up to 45 days, in order to allow time for the actual stamp to be delivered.

The Secretary reserves the right to terminate a state's ability to issue electronic stamps if the state violates any terms of the application. The state may also terminate their authority if they so choose.

Similar Legislation: On January 23, 2012, the House of Representatives passed similar legislation, H.R. 3117, by a roll call vote of 373-1. The RSC's Legislative Bulletin for H.R. 3117 can be found here.

Outside Groups Supporting:
- Congressional Sportsmen's Foundation
- Ducks Unlimited

Committee Action: H.R. 1206 was introduced on March 14, 2013, and was referred to the House Natural Resources Subcommittee on Fisheries, Wildlife, Oceans, and Insular Affairs. The full committee held a markup on April 24, 2013, and the legislation was favorably reported by unanimous consent.

Administration Position: No Statement of Administration Policy is available.

Cost to Taxpayers: CBO estimates that enacting H.R. 1206 would affect direct spending and revenues; therefore, pay-as-you-go procedures apply. Under current law, amounts collected from the sale of duck stamps are deposited in the Migratory Bird Conservation Fund and are available to be spent without further appropriation for waterfowl conservation projects. CBO estimates that the net effects of enacting the bill would be insignificant for each year and over the 2014-2023 period because the legislation would not have a significant impact on the number of federal duck stamps purchased. CBO's report can be viewed here.

Does the Bill Expand the Size and Scope of the Federal Government?: No.

Does the Bill Contain Any New State-Government, Local-Government, or Private-Sector Mandates?: According to CBO, H.R. 1206 contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act and would impose no costs on state, local, or tribal governments.

Does the Contain Earmarks/Limited Tax Benefits/Limited Tariff Benefits?: No.

Constitutional Authority: Rep. Wittman's statement of constitutional authority states: "Congress has the power to enact this legislation pursuant to the following: Article I, Section 8, Clause 3 of the Constitution of the United States." The statement can be viewed here.

RSC Staff Contact: Curtis Rhyne, Curtis.Rhyne@mail.house.gov, (202) 226-8576.

H.R. 885 - San Antonio Missions National Historic Park Boundary Expansion Act of 2013 *(Doggett, D-TX)*

Order of Business: The bill is scheduled to be considered on June 3, 2013, under a motion to suspend the rules and pass the legislation.

Summary: H.R. 885 amends the boundaries of the San Antonio Missions National Historical Park to include an additional 137 acres. The legislation prohibits the Secretary from acquiring this land by condemnation. Any land received will be by donation or exchange only. The legislation prohibits private property or non-federal public property from being included within the boundaries of the park without the consent of the property owner.

According to House Report 113-070:

> H.R. 885 would expand the boundary of the San Antonio Missions National Historical Park in Texas to include approximately 137 additional acres. Of the proposed expansion, 118 acres are currently owned by the National Park Service (NPS) or are being donated to the park. The remaining 19 acres would continue to be managed under a cooperative agreement with the city of San Antonio and Bexar County, which own the property.

After an NPS evaluation, it was determined that these additional acres are necessary to protect park resources and achieve the purposes of the park. Additionally, cultural and archeological resources associated with the park are currently outside the boundary, but would be included in this expansion.

Similar Legislation: On January 23, 2012, the House of Representatives passed similar legislation, H.R. 3117, by a roll call vote of 373-1. The RSC's Legislative Bulletin for H.R. 3117 can be found here.

Committee Action: H.R. 885 was introduced on February 28, 2013, and was referred to the House Natural Resources Subcommittee on Public Lands and Environmental Regulation. The full committee held a markup on April 24, 2013, and the legislation was favorably reported by unanimous consent, as amended.

Administration Position: No Statement of Administration Policy is available.

Cost to Taxpayers: CBO estimates that implementing H.R. 885 would have no significant impact on the federal budget. CBO's report can be viewed here.

Does the Bill Expand the Size and Scope of the Federal Government?: Yes. The legislation potentially increases the size of the San Antonio Missions National Historical Park by 137 acres.

Does the Bill Contain Any New State-Government, Local-Government, or Private-Sector Mandates?: According to CBO, H.R. 885 contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act and would not affect the budgets of state, local, or tribal governments.

Does the Contain Earmarks/Limited Tax Benefits/Limited Tariff Benefits?: No.

Constitutional Authority: Rep. Doggett's statement of constitutional authority states: "Congress has the power to enact this legislation pursuant to the following: Article I, Section 8, Clause 18 of the United States Constitution." The statement can be viewed here.

RSC Staff Contact: Curtis Rhyne, Curtis.Rhyne@mail.house.gov, (202) 226-8576.

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