Public Pharma Legislation Drafting Quick Guide

Lessons from California & Other States

Columbia Law School | Science, Health & Information Clinic

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Crafting legislation authorizing public pharma and its funding

Appropriate money: Authorizing legislation is the optimal moment to allocate long-term funding. It can be dangerous otherwise. For example, Washington's legislature authorized the state to purchase and distribute insulin in 2021, but the state has never actually done so because the statute didn't simultaneously provide funding. In California, the state health department secured a one-time appropriation of $100 million for the CalRx initiative in the state's 2022 Budget Act (and has received more money since), which ensured the initiative would get underway.

Authorize hiring of public officials: Building expertise *inside* the state's public health agency is essential for any state that aspires to manufacturing drugs "fully publicly" in the future. Public health experts can advise on everything from contracting, manufacturing, distribution, FDA approval, and public oversight. In California, the public agency's office supervising CalRx is sorely understaffed. Instead of hiring more public employees, the state is outsourcing much of its CalRx work to consultants and its private contractor, which increases costs to the agency in the long run and fails to build public capacity it could call on in the future.

Create market for the insulin and other products: Authorization statutes should preemptively address distribution challenges by including a mandate that public agencies, PBMs, and private pharmacies procure, use, and/or carry the state's low-cost products. Statutes can also mandate that insurers cover the state's low-cost products or at least charge patients prices no higher than the price of the state product. California missed this opportunity to guarantee a sizable market for CalRx upon first authorization, and has subsequently enacted a separate statute to that effect.

Guarantee public oversight: The authorizing statute gives states an opportunity to "hard-wire" good transparency rules and patient-centric governance structures into the public-private partnership *before* it is contracted. Language in the statute that limits future discretion in contracting could preemptively avoid some of the mistakes that California made in the CalRx contract. California now faces criticism for the opacity of its private partner, which has faced unexpected and unexplained delays that have cast doubt over the entire CalRx initiative.

Include multiple insulin products: The statute should provide for the development and commercialization of multiple insulin products across the range of onset, peak time, and duration, as many people living with diabetes require both short- and long-acting insulin and state laws typically require insurance plans to offer multiple products. Offering a full "suite" of insulin products will also make it easier for the public manufacturer to break into the market because insurers must offer a complete set of insulins to patients, and tend to do so with insulins all from the same manufacturer.

Maintain control of intellectual property (IP) rights and regulatory filings: Requiring that the private partner provide the public agency unredacted summaries of the material information it sends to regulatory authorities related to the products (as California did) increases the chances that the state learns of every aspect of the development and approval process to later apply to its own "fully public" development efforts. Maintaining control over the products' IP rights is also essential to prevent the state from becoming a "captive" customer of the partner, and preventing the partner from using public funds and resources to ultimately keep the benefits that flow from developed drugs for itself.