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On behalf of the California Healthcare Institute (CHI), whose more than 250 members include our state's premier life sciences companies and academic research institutions, I appreciate the opportunity to provide comments on the California Green Chemistry Initiative.

California's life sciences community is the global leader in biomedical research and innovation. More than 2,700 biomedical companies and 100 public and private research institutions in the state continue to advance scientific knowledge and develop breakthrough treatments, medical technologies and diagnostics to address serious ailments such as cancer, diabetes, HIV/AIDS as well as cardiovascular, respiratory, neurological, and infectious diseases. California's life sciences industry is also an important engine of economic growth, employing more than 267,000 workers statewide - with an average salary of \$71,300, and investing some \$27 billion annually into R&D - over 44% of total cash for the typical biomedical company.

Despite being one of the state's most successful industries, it is also one of the most regulated. Biomedical innovation takes place in a fragile, symbiotic environment composed of basic science research, intellectual property protections, private investment, and an extensive regulatory framework. Central to our industry is the rigorous Food and Drug Administration (FDA) approval process that assures patients they are getting the best and safest products available. This long and arduous process, often taking over 15 years and \$1 billion dollars to bring a biopharmaceutical product from the bench to the market place, requires a huge amount of investment with no real assurances of commercial success. This is especially true for the majority of small biopharmaceutical companies, with no revenue streams to fall back on, striving for the next great breakthrough on a limited amount of venture capital dollars. Although the timeframe for approval of medical devices and diagnostics is different, similar challenges face that segment of the industry. FDA approval is still required and the timeframes still take many years.

In order for the FDA to uphold its stringent safety and efficacy standards, a huge amount of clinical data is submitted to assure the agency that product, and the process of manufacturing that product, can be created in a way that guarantees the public will not be put at risk. Quality control procedures are extremely important to show consistency of the products in design as well as function. As part of these approval processes, the biomedical industry is required to use certain chemicals to achieve these outcomes. Despite the use of chemicals that can be hazardous and toxic at certain thresholds, it should be noted that

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California's biomedical industry is highly regarded as one of the "greenest" industries in the state, composed of companies and academic institutions that are renowned for their chemical use and disposal methods. The biotech industry can often use bench scale manufacturing methods to help keep hazardous material amounts to a minimum. comprehensive and stringent than those required by Federal Occupational Safety and Health Administration (OSHA).

Under the current robust permissible exposure limit (PEL)-setting process in California, an advisory committee takes input from labor representatives, industry and nationally recognized experts in the occupational health field and then reviews the scientific information and makes recommendations. The process includes sufficient worker protections and there is no evidence that employees are harmed by the current PEL settings for workplace chemicals. Further, California's permissible exposure limits are already the most stringent workplace chemical exposure limits of any state in the nation and is even more comprehensive and stringent than those required by Federal Occupational Safety and Health Administration (OSHA).

While CHI and our membership support the goals of the Green Chemistry Initiative, we are very concerned that certain command and control rulemaking or regulation could have significant negative consequences on our industry and the product approval process. If chemicals used in products, research or manufacturing are banned or exposure limits are altered, the FDA would require entirely new clinical trials to ensure such process modifications do not affect the safety or efficacy of the medical technology involved. Because clinical trials take years to conduct and cost tens of millions of dollars, such regulation would significantly disrupt research and development and manufacturing in California at a time when other states and countries are actively pursuing these innovative companies. In many cases, it may make more sense for a company to relocate, hindering California's ability to remain at the forefront of future innovation. This potential problem is compounded even further at a time in the FDA's history where a significant shortage of resources coupled with growing safety concerns and advancements in highly complicated technologies are already slowing down the approval process.

It is in that spirit that we offer the following as initial responses to your questions:

1. How much should the tax be on hazardous chemicals produced, used, or distributed in California?

CHI believes there should be no additional tax on hazardous chemicals produced in California. Instead, as an incentive for research and development by industry, there should be tax breaks for producing chemicals shown to be substitutes for more hazardous chemicals.

2. What information would trigger a ban of a chemical by the state of California? Banning of chemicals should have an extremely high bar, and then only executed if there are less hazardous marketplace alternatives or their use places individuals at risk of great immediate personal harm. Even a highly toxic chemical that is stable may be desirable if it can substitute for another chemical that is both highly toxic AND reactive. A science based risk analysis could be used to generate point values or hazard levels (some of these are already existent and should be used rather than reinvented at great expense). If chemical contamination is a problem (e.g. certain toys from China) than the specific contaminated item from the specific manufacturer should be not only banned but also recalled until it can be shown to be safe (similar to contaminated medicines or other products). It

should be noted that in the biologics industry, any change in manufacturing process, including use of intermediary chemicals, is subject to review and approval by the FDA. If a chemical necessary to the manufacturing process is banned, the resulting changes in process could have many consequences, up to and including a requirement for additional clinical trials.

3. What incentives should the state of California provide to promote the development of safer chemical or product alternatives? CHI believes incentives should drive this program. One incentive should be tax relief for substitution of less hazardous chemicals or products based on proven risk analysis, especially to those goods produced close to point of use in order to reduce GHG contributions from transportation. Awards and public recognition for companies that successfully develop chemical or product alternatives would also be helpful. Case studies and cost analysis help to show accurate ROI data and cost savings for cradle to cradle periods. Finally, specifically labeled products showing they are the result of these types of process improvements could also be a strong incentive.

4. What would be the appropriate response by the state of California for failure to use safer alternatives? The appropriate response would be to offer information and case studies of the benefits of using safer alternatives, with punitive measures only in those cases where worker or consumer safety becomes an immediate concern. Educational outreach is imperative and must take into account the wide variety of characteristics of the population. Some companies will have a much more difficult time implementing changes due to the nature of the business, and even for companies that can change quickly, some processes will not lend themselves to change and for some chemicals there will be no safer alternative. In nature, there are examples of microbes that thrive on sulfur and would perish in "clean" and safe environments. There must be room for a variety of perspectives and consideration on a case by case basis.

5. What would be the appropriate response by the state of California for failure to disclose product ingredients? If specific chemical names are not disclosed due to trade secret information, the risk profile of the chemical could be provided depending on the hazard class and the use threshold. Product ingredients MUST have a minimal level at which no disclosure is required in line with scientific dose response relationships. Failure to disclose information could have penalties that are weighted to the calculated risk of major environmental or health hazards that would result.

6. By what date should the state of California require reusable or biodegradable non-petroleum based packaging? Again, this should be based on realistic expectations of ratios of types of packaging that can be targeted in specific sectors, such as food, medicines, durable goods, etc. Some of these areas will be more aligned with special packaging types exactly for reasons of safety and sustainability. The data involved should also be compiled and categorized correctly before rollout to ensure the impact is real. In other words, standards of re-use and biodegradation should be established and communicated before regulations spawn a lot of misinformation and impractical compliance. Otherwise, as an example, one might have the little recycling triangle symbol with numbers 3-9 showing compliance while only numbers 1-2 can really be recycled easily and conveniently. A five and ten year plan should be developed with milestones and goals targeted during that span, with great consideration to products, such as pharmaceuticals and biologics, that may require other packing to maintain safety and efficacy of the product.

NEW QUESTION: How can industry use a multi-media standard, such as ISO 14000, to demonstrate they achieve performance above and beyond compliance with regulatory standards for product and processes?

Established third party certifications like these are becoming more common and acceptable for demonstrating high level EHS compliance programs. These may be used to at least put the company in a tier above typical companies and possibly below the tier of OSHA VPP and EPA Performance Track, although several companies with the latter may also have the former. As with the successful San Diego CUPA "EPIC" project, a reasonable result of being part of this tier of companies would be a reduction of the frequency and duration of regulatory inspections, thus resulting in a savings to the government of time and energy spent on already compliant sectors. The time and energy saved here would naturally have a better return on investment if redirected to the least compliant sectors.

Please contact me with any questions or concerns. We hope to continue working cooperatively throughout this process.

Sincerely,

Sandra Pizarro
Vice President, State Government Affairs