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RESEARCH ARTICLE

Economic Value of Initial Implementation Activities for Proposed Ban on Sales of Over-The-Counter Diet Pills and Muscle-Building Supplements to Minors

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Introduction: Over-the-counter diet pills, weight-loss supplements, and muscle-building supplements often contain harmful ingredients and are associated with eating disorder diagnoses and other negative health outcomes. This study estimated the value of state initial implementation activities, for example, regulation development, to implement a ban on the sale of dangerous over-the-counter diet pills and muscle-building supplements to minors.

Methods: We enumerated minimum, best, and maximum values for 22 inputs among 11 activities state employees may undertake if the legislation were signed into law. For employment costs, we estimated staff hours on the basis of data from 10 key informants and obtained salary ranges from a state government website. Data were collected and analyzed between September 2021 and January 2022. We calculated 95% CIs using 10,000 Monte Carlo simulations that varied inputs simultaneously and probabilistically. We conducted two sensitivity analyses using all minimum and all maximum salaries.

Results: The estimated value of state start-up activities was $47,536 (95% CI=$36,831−$57,381). Inputs with the largest impact on this estimate corresponded to combinations of the highest salary and greatest hours per task.

Conclusions: The state's one-time opportunity cost to initiate this age-restriction policy would be minimal considering potential health gains. Sensitivity analyses did not change the conclusion, especially if the state produces subregulations linked to existing law rather than new regulations.

INTRODUCTION

Owing to weak federal regulation of dietary supplements, over-the-counter (OTC) diet pills, weight-loss supplements, and muscle-building supplements have been repeatedly found to contain harmful and illegal ingredients, are often deceptively marketed, and are prospectively associated with eating disorder diagnosis and

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the onset of illicit anabolic steroid use.[1−5] Other than orlistat/Alli, all diet pills, powders, and teas on the U.S. market are sold as dietary supplements. The federal Dietary Supplement Health and Education Act of 1994 prohibits the Food and Drug Administration (FDA) from requiring proof of safety or efficacy of supplements before they enter the market; thus, the FDA is often not aware that a supplement is dangerous until after consumer injuries or deaths are reported to the agency.[4,6] As a result, diet pills and muscle-building supplements have been found to be adulterated with dangerous ingredients, including banned pharmaceuticals, anabolic steroids, and methamphetamines, which in turn may be responsible for adverse medical conditions, such as stroke, heart attack, and liver injury leading to emergency room visits, hospitalizations, and death.[6−9] In response, lawmakers in several U.S. states, including Massachusetts, are considering legislation to ban the sale of these products to minors[10−12] but have concerns regarding the start-up costs to the state. We estimated the value of state activities that may be required to implement a Massachusetts-proposed ban on the sale of OTC diet pills and muscle-building supplements to minors aged <18 years (2021−2022 legislative session, Bill S1545/H4271).[10]

METHODS

We extracted 6 key provisions (KPs) from the text of bill: (1) a ban on the sale of OTC diet pills/weight-loss supplements to minors aged <18 years, (2) a similar ban on the sale of OTC muscle-building supplements, (3) in-person vendors must move products behind a counter and/or to a locked case, (4) vendors must display a warning note at checkout, (5) the Massachusetts Department of Public Health is to identify which products will require photographic identification in consultation with the FDA and community stakeholders, and (6) vendors in violation will incur a fee of no more than $2,000.[10] Two of these provisions—moving products behind the counter or into a locked case and the violation fee—fell outside the scope of this analysis because they did not focus on the state's initial implementation activities. Table 1 displays the 11 anticipated activities, along with the corresponding KPs, which we identified state actors may need to undertake to implement the legislation.

Owing to the lack of relevant literature on state staffing costs to implement similar legislation, we conducted 10 key informant interviews (all virtual) between September 2021 and January 2022 to inform our model. Specifically, we sought data to calibrate our activity list and inform analyses relevant to the state agency and staff mixture, staff hours required, and federal resources regarding supplement safety. Key informants had previous job experience at relevant state agencies. We enumerated minimum, best, and maximum values for 22 inputs, 11 relating to anticipated activities and 11 showing the corresponding salary amounts (Table 1). Actual salary ranges and the benefits rate (38%) came directly from the state's jobs website.[13]

The best estimates for staff time (in full-time equivalents) were derived from key informants' input. Maximum time estimates were calculated as a 50% increase from the best full-time equivalent estimates. We set minimum time estimates for KP1 and KP2 at 0 because Section 3 of the bill states, "The Department of Public Health may promulgate such procedures, rules or regulations as necessary. . .."[10] This optionality creates flexibility—and more uncertainty—regarding the amount of time state actors will spend on developing regulations. For the remaining KPs, minimum time estimates were derived on the basis of our team's timed trial of assembling a list of impacted vendors to contact as well as specific inputs from key informants. We calculated 95% CIs by running 10,000 Monte Carlo simulations that allowed all 11 time-related inputs to vary simultaneously and probabilistically, along a PertBeta distribution. We conducted 2 sensitivity analyses using all minimum salaries and all maximum salaries. Best value estimates and corresponding 95% CIs are in 2021 U.S. dollars. Analyses utilized Palisade@Risk and Microsoft Excel.

RESULTS

We estimated that implementation activities would require 850 hours of staff time (minimum: 178; maximum: 1,275) divided among the 11 activities and 3 staffing levels. These activities represent a value of $47,536 (95% CI=$36,831−$57,381) for one-time opportunity costs to the state. Because all 11 variables in the Monte Carlo simulations had the same components (minimum, best, or maximum time estimates × mid-point salary), the variables that had the greatest impact on the estimate were those combining the highest salary with the greatest hours-per-task amounts (Figure 1). For the sensitivity analyses, the value was estimated at $28,565 (95% CI=$22,645−$34,110) when using only minimum salaries and at $66,507 (95% CI=$50,928−$80,745) when using only maximum salaries for all staff.

DISCUSSION

This study elucidates a rarely published phenomenon, namely, the value of the time spent by public employees in the earliest stages of implementing new policies. In this case of the proposed ban on the sale of harmful

Table 1. Inputs Estimating One-Time Implementation Opportunity Costs Banning Sale of Dangerous Over-The-Counter Supplements to Minors (Massachusetts, 2021)

Key provision	Activity	Staff level[a]	Parameter values (FTEs), PertBeta distribution[b]			Midpoint annual salary[c]
			Minimum	Best	Maximum	
KP1[d] and 2[e]	Write regulations	Counsel II, AG[f]	0.000	0.014	0.022	$90,470
KP1 and 2	Write regulations	Counsel II	0.000	0.014	0.022	$89,288
KP1 and 2	Write, shepherd, and approve regulations	Management VIII	0.000	0.111	0.166	$97,414
KP4[g]	Draft note for display at checkout	Counsel II	0.001	0.005	0.007	$89,288
KP4	Draft and approve display note	Management VIII	0.000	0.014	0.022	$97,414
KP5[h]	FDA and community consultation	Management VIII	0.012	0.038	0.058	$97,414
KP5	Develop guidelines on banned products for vendors	Counsel II	0.008	0.014	0.022	$89,288
KP1, 2, and 5	Write, shepherd, and review guidelines for vendors	Management VIII	0.029	0.077	0.115	$97,414
KP1, 2, and 5	Assist with regulation/ guidance development	Business management specialist	0.023	0.082	0.123	$70,991
KP1, 2, 4, and 5	Assemble a list of impacted vendors	Business management specialist	0.002	0.010	0.014	$70,991
KP1, 2, 4, and 5	Advise vendors of new requirements	Business management specialist	0.012	0.029	0.043	$70,991

Note: FTE is the percentage of effort in 1 year of a full-time employee; 1.0=2,080 person-hours of labor.
[a]The following data sources informed all estimates: key informant interviews and authors' estimates. In addition, all activity estimates were varied simultaneously for 10,000 Monte Carlo simulations.
[b]All salary amounts came from Massachusetts' official job posting website.[13]
[c]These are illustrative job titles only that represent high-, mid-, and low-level staff undertaking the given activities.
[d]KP1: Ban sale of over-the-counter diet pills/supplements to minors aged <18 years.
[e]KP2: Ban sale of over-the-counter muscle-building supplements to minors aged <18 years.
[f]All staff are in the Department of Public Health unless otherwise noted.
[g]KP4: Warning note for display at checkout counter.
[h]KP5: Department of Public Health to identify products (including by consulting experts, FDA, and eating disorder experts) impacted by the legislation.
AG, Attorney General's office; FDA, Food and Drug Administration; FTE, full-time equivalent; KP, key provision.

OTC diet pills and muscle-building supplements to minors in Massachusetts, we estimated that it would not require more than $48,000 worth of state agency staff time during the 1-time initial implementation period. Even in the unlikely scenario that all staff involved were paid maximum salaries, the estimate only reaches $66,507. These values fall below or within the starting annual salary range of an administrative secretary in Massachusetts.[13] Moreover, because the bill does not mandate brand new regulations, state agencies may decide to produce subregulations or guidelines linked to existing regulations, which would reduce the time—and therefore the opportunity cost—required for implementation.

We compared the proposed legislation with tobacco laws, which are most similar in age-restricted sales at the state and federal levels.[14] However, tobacco laws are funded through state and federal avenues, and S1545/ H4271 bill has no new funding attached, which may place an additional administrative burden on state staff

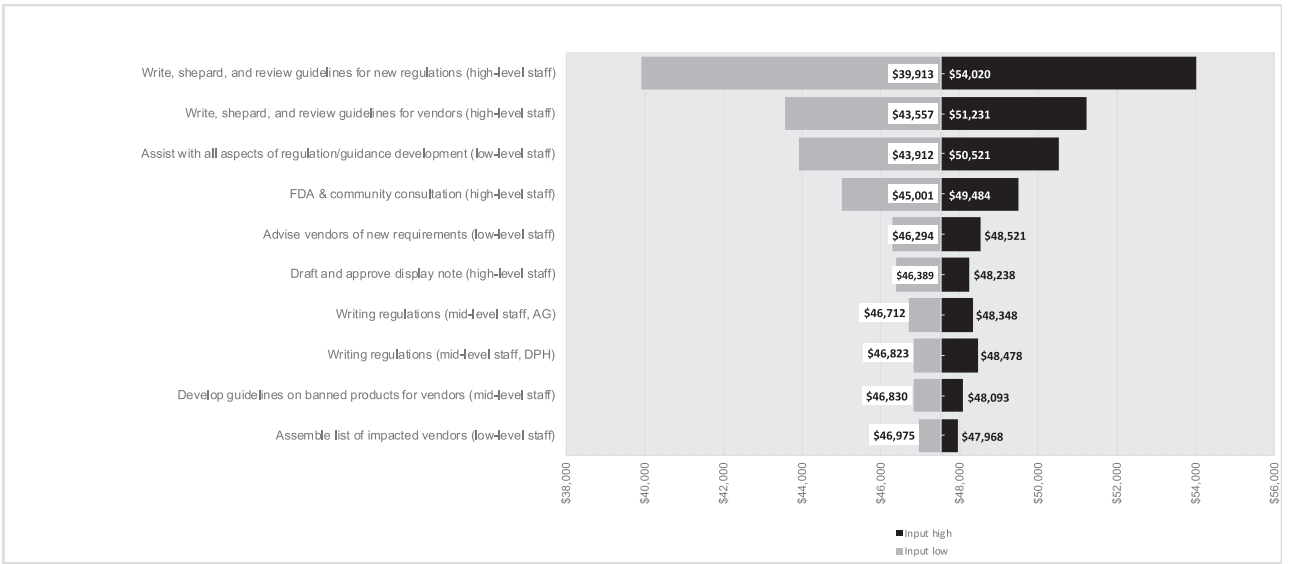

Figure 1. Estimated opportunity costs for implementation activities: Top 10 inputs ranked by effects on output mean.

and/or displace current work tasks.[15] Legislators and stakeholders can support state agency staff to further reduce the implementation hours. For example, as stipulated in the legislation, state staff should consult with the FDA and expert community stakeholders. Those same stakeholders could generate and share with state staff a list of products affected by this legislation to reduce implementation burden and cost.

Because specific provisions and salary ranges may vary across states, individual states may want to replicate this analysis to incorporate these differences. In addition, cost-effectiveness studies would elucidate the broader impact of this legislation, including enforcement costs, costs borne by vendors and municipalities, and the net benefit (or cost) to society. The next steps would include this type of analysis for 1 or more of the states considering similar legislation.

Limitations

A key limitation of this study is the amount of uncertainty around time-per-task estimates owing to the lack of relevant literature. To compensate, we relied on knowledgeable informants for the starting points and then ran 10,000 simulations rather than a more typical 5,000 and allowed all 11 of the time-per-task estimates to vary, even though some tasks were estimated to need relatively few hours. Furthermore, future studies are needed to estimate the immediate and longer-term economic impacts in this and other states considering banning the sale of these dangerous products to minors, including from multiple perspectives. For example, from the state's perspective, we anticipate the postimplementation period to have less fiscal impact because no further regulation promulgation would be required, and the list of impacted supplements will need only updating. In contrast, costs to vendors may increase depending on whether they incur fines for violating the new law.

CONCLUSIONS

This study elucidated the opportunity cost for a state-level governmental body to conduct the first activities involved in enacting a new prevention policy. Because this can be considered a start-up cost, it is typically excluded from traditional cost-effectiveness studies,[16] despite being of considerable interest to members of the Legislature. We found that the expected opportunity costs to the state would be minimal to implement a ban on the sale of dangerous OTC diet pills and muscle-building supplements to minors, which may in turn reduce the incidence and relapse of eating disorders and illicit anabolic steroid use and thus abate negative health outcomes.

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