Too Little, Too Late

Too Little, Too Late: Ineffective Regulation of Dietary Supplements in the United States

Ranjani R. Starr, MPH

Millions of people in the United States consume dietary supplements hoping to maintain or improve their health; however, extensive research has failed to demonstrate the efficacy of numerous supplements in disease prevention. In addition, concerns about the safety of routine and high-dose supplementation have been raised.

The Food and Drug Administration regulates dietary supplement quality, safety, and labeling, and the Federal Trade Commission monitors advertisements and marketing; still, vast enforcement challenges remain, and optimal governmental oversight has not been achieved. If the composition and quality of ingredients cannot be reliably ensured, the validity of research on dietary supplements is questionable. Moreover, the health of the US public is put at risk. (*Am J Public Health.* 2015;105:478–485. doi:10.2105/AJPH.2014.302348)

THE NUMBER OF DIETARY supplements (see the box on the next page[1]) sold in the United States has dramatically increased since the passage of the Dietary Supplement Health and Education Act (DSHEA), from about 4000 when law went into effect in 1994 to more than 90 000 in 2014.[2,3] Approximately 150 million persons in the United States use dietary supplements, with 79% reporting daily use and 10% taking 5 or more per day.[4,5] Botanical dietary supplements are used by 17.9% of US adults.[6] Persons in the United States report using dietary supplements to maintain or improve overall health and the health of specific organs, prevent disease, increase energy, improve mental health, achieve weight loss, and resolve miscellaneous health issues such as menopause and hot flashes.[7,8] Only 22% reported using them to supplement their diet.[7] Almost 23 million US persons report using dietary supplements instead of drugs, and 30 million use them instead of over-the-counter medications.[9]

Dietary supplement use has grown despite insufficient evidence to demonstrate clear health benefits for most and concerns of increased health risks for several.[7,10–14] Nine in 10 health food stores suggest dietary supplements for treating a variety of illnesses, from hypertension to cancer.[15–19] Limited evidence of efficacy exists for some dietary supplements; however, serious safety issues and drug supplement interactions have been documented.[20–22] One study has estimated that at least 1 in 12 US adults takes botanical dietary supplements known to cause kidney damage; other dietary supplements are known carcinogens, hepatotoxins, hormone modulators, and sympathomimetics.[23,24] Dietary supplements may be adulterated with dangerous compounds, be contaminated, fail to contain the purported active ingredient, or contain unknown doses of the ingredients stated on the label; be sold at toxic dosages; or produce harmful effects as a result of their interaction with other drugs.[9,25] Additional safety issues may arise from megadosing, which three quarters of persons in the United States believe can produce greater health benefits than taking the daily recommended value.[26] For several vitamins and minerals, a U-shaped relationship between supplement dosing and mortality has been observed, indicative of substantial toxicity with high-dose supplementation.[27–29] As many as a third of calls to poison control centers associated with dietary supplements report such adverse events (AEs) as coma, seizure, myocardial infarction, liver failure, and death.[30]

Despite extensive research on dietary supplements, little attention in public health has focused on challenges in their regulation. The regulatory aspects of the dietary supplement industry provide context for several areas of public health interest, including consumer behavior with respect to use, safety, and efficacy and research focused on health effects of routine supplementation.

DIETARY SUPPLEMENT REGULATION IN THE UNITED STATES

The dietary supplement industry is regulated by the Food and Drug Administration (FDA), primarily under provisions of DSHEA.

Regulatory Definition

DSHEA's definition of dietary supplements is provided in the box on the next page.[1] Dietary supplements include sports performance products, weight loss medications, protein powders, and a variety of herbal remedies.[31] Although originally intended to be products that increase one's dietary intake, several dietary supplements, including androstenedione, shark

US Federal Government Definition of Dietary Supplements

According to the Dietary Supplement Health and Education Act of 1994, dietary supplements include a large heterogeneous group of products intended to supplement the diet that are not better described as drugs, foods, or food additives. Supplements may contain, in whole or as a concentrate, metabolite, constituent, or extract, any combination of 1 or more vitamins, minerals, amino acids, herbs or other botanicals, and other substances used to increase total dietary intake, including enzymes, organ tissues, and oils. They must be intended for ingestion; sold in the form of capsules, tablets, soft gels, gel caps, powders, or liquids; and not be marketed as food items.

Source. Dietary Supplement Health and Education Act of 1994.[1]

cartilage, and melatonin, are not common dietary items.[32–34]

Safety and Efficacy

The DSHEA prohibits supplements that pose a substantial risk of injury, allows the Secretary of Health and Human Services to issue immediate bans on substances that are imminent hazards, and authorizes the FDA to implement current good manufacturing practice (cGMP) guidelines.[35] The law also requires premarket notification for new dietary supplements, defined as supplements that were not marketed in the United States before October 15, 1994.[1] Products violating these regulations are deemed dangerous, adulterated, misbranded, or otherwise unlawful.[35–37]

However, supplements need not be evaluated for efficacy, and only limited data on safety are required for new supplement ingredients.[37] No notification is needed for products not containing a new ingredient.[38] FDA authority is limited in regulating supplements sold before October 1994.[39] Supplements may theoretically be marketed at any concentration, as long as the daily recommended value, if available, is specified on the label.[40] For example, vitamin D_3 is widely available in 50 000 international-unit doses, with the supplement label stating that each dose provides 12 500% of the daily recommended value. When the daily recommended value is undetermined, supplements may be marketed without this information.[40] Supplements may also be sold in any combination of ingredients.[41]

Notification of New Ingredients

Although notification of new ingredients in dietary supplements is a regulatory requirement of DSHEA, implementation has been problematic. Between 1994 and 2012, despite thousands of supplements introduced to US markets, the FDA received sufficient notification of new ingredients in only 170 supplements, representing only the tip of the iceberg.[39] Identifying violators, however, is difficult; over 10 months in 2013, the FDA issued warning letters to 37 manufacturers about 55 products considered dangerous or adulterated.[42] These products contained compounds deemed new supplement ingredients, including ones that are currently sold as prescription drugs, analogs of compounds sold as prescription drugs that have never been tested for safety, drugs that have been withdrawn from US markets for safety reasons, and other compounds with known or unknown safety issues; the FDA had not been notified about these ingredients, and the ingredients were not listed on the supplement label.[42]

Although the DSHEA enables the FDA to evaluate premarketing evidence of safety for new ingredients, this aspect of the law has not been fully implemented because guidelines for what evidence is sufficient to establish safety have not been finalized.[39] Draft guidance proposed in 2011 is still in the comment period, and no final ruling has been issued.[43] Even if implemented, concerns remain that the guidelines would improve but not resolve safety issues because they give undue credit to historical use, do not require premarketing safety studies in humans, and allow manufacturers to cherry-pick favorable results to submit to the FDA.[39] Moreover, under DSHEA, it remains legal for a company to sell a supplement containing new ingredients, even if deemed unsafe, until the courts rule in the FDA's favor.[39]

Quality Assurance

In 2007, the FDA published cGMP guidelines, including requirements for manufacturers to test products to ensure product quality, confirm the absence of some contaminants, verify accuracy of labeling, maintain minimum standards for manufacturing and packing, monitor AE reports, and make all records available for FDA inspection; their purpose was to ensure internal consistency in product quality.[44] However, these established guidelines do not address the underlying safety of the supplement itself.[45] Moreover, they remain nonbinding on the manufacturer.[44] As a result, manufacturers are reticent to adopt the FDA cGMP guidelines for botanical supplements, which can vary substantially in strength and quality depending on genetic variety and environmental conditions of the plants from which they are derived.[37]

Despite the cGMP ruling, a 2010 US Government Accountability Office report revealed that an analysis of 40 dietary supplements for the presence of lead, arsenic, mercury, cadmium, or pesticides found trace amounts of 1 or more of these contaminants in 93%.[15] In 2011, 73% of supplement manufacturers inspected by the FDA failed to adhere to 1 or more regulations.[4] One study reported that 59% of tested

botanical supplements contained plant species not listed on the label; additionally, active ingredient substitution was observed among 83% of companies tested.[46] Poor compliance may be attributed, at least in part, to inadequate enforcement; in 2013, the FDA inspected only 416 supplement manufacturers for cGMP adherence, representing 10% of the estimated 4000 manufacturers covered by cGMP regulations and 2.8% of the 14 995 domestic and international dietary supplement firms registered with the FDA.[47]

Additional limitations of the cGMP guidelines extend even to manufacturers who implement them fully. Because manufacturers set their own standards, the same product from different manufacturers may not be equivalent in composition, strength, or bioavailability.[48] Manufacturers are not required to confirm the identity of all ingredients supplied to them, and following cGMP guidelines does not guarantee the absence of all contaminants.[48] Moreover, unlike drugs, which are considered adulterated or misbranded if they do not achieve compliance with national standards set by the US Pharmacopoeia and National Formulary, dietary supplement manufacturers may choose whether to be compliant[48]; only 6 brands of dietary supplements are currently verified by the US Pharmacopoeia.[49] A recent study comparing actual to expected concentrations of vitamin D_3 in commercially available brands revealed unacceptable deviations, with pill potency ranging from 9% to 146% of the stated concentration; variability was within acceptable range only for US Pharmacopoeia–verified supplements.[50] Substantial variability in botanical supplement composition and concentrations has also been noted.[16]

Monitoring Safety

The primary mechanism for monitoring supplement safety is a voluntary reporting system established by the FDA Center for Food Safety and Applied Nutrition, called the Center for Food Safety and Applied Nutrition AE Reporting System (CAERS). An Office of the Inspector General report revealed that fewer than 1% of all AEs are reported through CAERS, and enforcement is further limited by inconsistencies in the data.[9] In 2006, the Dietary Supplement and Nonprescription Drug Consumer Protection Act mandated reporting of serious AEs by supplement manufacturers; serious events were defined as deaths or life-threatening events, initial hospitalizations or prolongations of stay, disabilities or other permanent impairments, congenital anomalies or birth defects, or other serious medical events requiring intervention to prevent permanent damage or death associated with supplement consumption.[51] The act required supplement labels to contain the manufacturer's contact information for use by consumers to submit AE reports.[51]

Despite the ruling, a 2009 Government Accountability Office report revealed that the FDA received only 596 serious and 352 mild or moderate AE reports in a 10-month period in 2008, although the estimated number of AEs occurring annually in the United States is closer to 50 000[2]; in 2011, the number of AEs reported to the FDA rose to 2480 per year but still fell short of the number reported to the American Association of Poison Control Centers.[4] Moreover, an analysis by the FDA revealed that 64% of voluntarily reported mild or moderate AEs met criteria for serious events, revealing that many AEs are missed as a result of misclassification.[4]

Challenges to successful implementation of CAERS include the following: It relies on consumer awareness of AEs associated with supplement use and knowledge of the FDA's role in monitoring supplements; it only requires AE reports to be submitted if they contain a minimum number of data elements, although information on required data elements is not provided to consumers; there is no legal liability to report serious AEs lacking the minimum data elements; the FDA's ability to causally link supplement use to adverse outcomes is compromised because medical records or product samples are not required; and manufacturers are not required to forward to the FDA reports of AEs made to other agencies (state health departments, physicians, media, poison control centers, etc.).[31,36] As a result, many of the deficiencies noted before the act have not been adequately addressed.[9] Notwithstanding these shortcomings, the absence of data is falsely reassuring and hampers the FDA's efforts to gain legislative support for regulatory changes.[37]

Health Claims

Dietary supplements may not claim to treat, prevent, diagnose, mitigate, or cure a specific disease (disease claims). However, they can contain general health claims, nutrient content claims, or structure–function claims.[31] Some scientific validation must be submitted to the FDA only for health claims, which establish a direct link between supplement use and reduced risk for disease. Scientific validation needs to be maintained on file only for structure–function claims, which state that a supplement maintains, supports, stimulates, regulates, or promotes good body function.[31,52]

Criteria for the rigor of evidence needed to support a claim have not been established; scientific evidence may be provided by just 1 article that has not achieved recognition or agreement.[52,53] Claims may be made with even less scrutiny if incorporated into the product name or through pictures on the label.[52] Manufacturers displaying claims must include a disclaimer on the label stating that the claims have not been evaluated by the FDA.[54] However, research has shown that consumers tend to ignore disclaimers, especially when presented in a small font, away from the health claim, and using confusing terminology; because no display requirements for disclaimers exist, poor practices are commonplace.[52,54,55]

Several deficiencies and potentially deceptive practices in supplement labeling have been documented in the literature. A 2003 Office of Inspector General investigation confirmed that

most supplement labels are misleading, uninformative, and inconsistent and that consumers experience considerable difficulty interpreting supplement labels correctly.[54] Claims analyzed were poorly understood, and labels often failed to state the intended purposes of the supplement, did not identify the active ingredient, provided insufficient information to extrapolate active ingredient concentrations, used jargon that implied but did not provide clarity on product quality, and did not contain information on contraindications, known interactions, or side effects.[54] Despite the dangers of megadosing, 85% of labels inspected did not contain information regarding the maximum dose.[54]

Advertising and Marketing

Marketing is an important area of enforcement because nearly two thirds of persons in the United States report exposure to dietary supplement advertising.[56] The Federal Trade Commission (FTC) regulates supplement advertising, including print and Internet ads, infomercials, catalogs, and other manufacturer materials, to ensure that advertising is "truthful, not misleading, and substantiated."[52(p434),57] Despite these requirements, a study commissioned by the FTC found that the majority of US persons are overly optimistic about the results they can achieve.[58]

A guidance document released by the FTC in 1998 contains nonbinding recommendations, and advertisements do not require preapproval.[59,60] Case law has strengthened the criteria the FTC uses to identify misleading, untruthful, or unsubstantiated advertising.[57] However, in recent years, courts have shifted from a stance of consumer protection to one in which the freedom of speech of supplement manufacturers is upheld.[61,62] Specifically, courts have opined that federal regulations that unduly restrict commercial speech are unconstitutional. Moreover, they have applied a higher standard for demonstrating that a claim is misleading, arguing that inconclusive scientific evidence or overstated health benefits are not sufficient to justify that a health claim is misleading.[55,61,62] Despite the recognized inefficacy of disclaimers,[55] courts have ruled that their use in conjunction with unsupported health claims is more consistent with commercial free-speech rights than are outright bans.[61,62]

Additionally, postmarketing surveillance remains a challenge. A study found that 55% of Web sites selling supplements made disease claims; half of these Web sites did not contain the required disclaimer.[63] Even higher rates (85%) of disease claims were found among supplement advertisements displayed in non-English newspapers.[64] A 2010 Government Accountability Office investigation confirmed that despite monitoring efforts, supplement manufacturers continue to make false and dangerously misleading claims about products, ahead of detection by the FTC.[15]

Enforcement Challenges

Despite many provisions, enforcement of DSHEA remains a formidable challenge. DSHEA places the burden of proving that a supplement is unsafe, or marketed without adequate notification or proof of safety, on the FDA.[35] The FDA has to demonstrate that a product is unsafe at the serving size, under usage conditions, and for its intended purpose as specified on the manufacturer's label.[31,45] Off-label usages resulting in adverse outcomes cannot be used to demonstrate a lack of product safety, even if the supplement is typically used in that manner.[32] These provisions apply even after an immediate ban is issued on a product because the FDA must promptly withdraw the ban if it cannot provide substantive proof.[35] Moreover, it remains legal for manufacturers to continue selling the product until the FDA successfully defends a ban in court.[41]

The DSHEA requires that each case of alleged adulteration of supplements be tried *de novo*; in other words, a legal precedent in the matter cannot be used to influence future outcomes.[35] Theoretically, if a manufacturer swaps 1 dangerous ingredient in a dietary supplement for a closely related chemical analog, the years of progress made by the FDA in banning the first ingredient may be rendered inconsequential.[25] Many supplements are on the market today, including some banned in other countries that meet criteria for being dangerous substances.[36] Because the FDA uses a case-by-case approach to enforcement, these supplements remain for sale at thousands of retailers.

Ineffective enforcement may also be ascribed to logistical challenges. An Office of Inspector General report noted that 28% of supplement manufacturers fail to register with the FDA; in addition, the FDA lacks accurate contact information for 20% of registered supplement manufacturers.[65] Not surprisingly, only 69% of dietary supplements issued Class I recalls between 2004 and 2011 were successfully withdrawn.[66]

Although some laws were passed by states to achieve stricter control over ephedrine, state legislation may not be a viable mechanism to strengthen supplement regulation. Laws with stricter requirements for dietary supplements may be interpreted as interfering with, or being in contradiction to, the congressional intent behind DSHEA of increasing consumer access to supplements and therefore be subject to preemption on the basis of the US Constitution's Supremacy Clause.[33,37] State laws may also inadvertently violate the Commerce Clause, which prohibits legislation whose impact on interstate commerce is more than incidental or that imposes a burden on manufacturers that is in excess of its purported benefit.[37]

DISCUSSION

Consumers are drawn to dietary supplements as a result of their easy accessibility, cultural and historical uses, low cost, appeal as natural cures, and presumption of safety and efficacy; a desire for self-reliance in matters concerning their own health; or because they feel disenfranchised by traditional medicine.[67] Consumers may be misled by words such as "natural" or "clinically

tested" and be less likely to recognize dangers associated with products containing these on their labels.[36,54]

Supplements are marketed side by side with drugs that make FDA-approved treatment claims and disclose their side effects, persuading the US public to believe that supplements and drugs are 2 equally efficacious alternatives, with supplements weighing in as cheaper and more natural, with fewer side effects.[26] Dietary supplements as a cost-effective alternative may be especially appealing to vulnerable populations with no other access to powerful prescription medications[68]; coincidentally, these groups often have low health literacy, making them less likely to be critical of misleading claims.[69]

Most supplement users believe dietary supplements are both safe and effective and assume that supplements are regulated similarly to over-the-counter drugs.[70] According to a 2002 Harris Poll, 50% of US persons believe that dietary supplements are approved by the government, and two-thirds believe that supplement labels are required to contain warnings about dangerous side effects.[2,71]

Because supplements are purchased without medical prescriptions, Americans look to manufacturers and retailers of supplements for health information; as a result, the information available to consumers is skewed toward commercial interests, making them victims of hyperbolic advertising and misleading claims.[15,52] This is concerning because 87% of consumers report obtaining information on supplements from friends, family, magazines, books, health food stores, and television, and only 13% consult with physicians or pharmacists.[72] That fewer than half of supplement consumers report supplement use to their physicians is of further concern because 72 million users of dietary supplements are also prescription drug users, among whom the risk of supplement–drug interactions is high.[6,73,74] Few consumers are aware of supplement–drug interactions.[36,75]

Inadequate Assurance of Safety and Efficacy

The predominant challenge in a passive, postmarket regulatory framework is the poor timeliness of the FDA's response and a laissez-faire attitude toward the individuals whose lives are inadvertently sacrificed or severely compromised in the process of generating the proof necessary to ban the product.[36] It is paradoxical to acknowledge supplements as substances capable of improving health but not consider them drugs. As pharmacologically active substances, they are equally at risk for producing side effects and adverse outcomes through nonselective interactions. It is misleading that manufacturers can promulgate a product's potency and efficacy at the same time as they claim that it is harmless.[38] Furthermore, even for the safest dietary supplement, the risk for adverse outcomes from supplement–drug interactions cannot be eliminated. Consequently, the occurrence of disease outbreaks linked to dietary supplements is not surprising. Absent adequate governmental protection, individuals in the United States have essentially become clinical trial participants for dietary supplements, including those with new, untested ingredients, without their knowledge or consent.[33,36]

Moreover, insufficient attention has been paid to supplement efficacy. As with foods, the efficacy of dietary supplements need not be established. However, unlike foods, which may be consumed for taste or hunger regardless of nutritive value, dietary supplements are primarily taken for their purported therapeutic benefits.[76] Therefore, even supplements that may have no safety concerns are not harmless because they are products consumed with no presumable benefit.[36]

Despite substantial differences in regulatory control over drugs and dietary supplements, pharmaceutical giants have remained mostly silent on regulatory issues concerning dietary supplements. This is perhaps because pharmaceutical companies have a substantial stake in the dietary supplement market.[77,78] In the past decade, portfolio diversification has been an important strategy by which big pharma has addressed its burgeoning costs and declining profits.[79,80] Dietary supplements, which are cheap to make and not burdened with regulatory hurdles, represent a significant and growing sector, with sales exceeding $30 billion in 2011.[4]

Public Health Research

Public health research on dietary supplements has heavily focused on efficacy, with large studies and systematic reviews concluding that the evidence to support routine supplementation for primary prevention of chronic diseases is inadequate.[10–14] The US Preventive Services Task Force has concluded that there is insufficient evidence to recommend single-nutrient, paired-nutrient, or multivitamin supplementation for the prevention of cardiovascular disease and cancer or vitamin D_3 and calcium supplementation, either alone or in combination, for the prevention of fractures.[81,82] However, the impact of regulatory challenges may not have been adequately considered in these studies. As noted by the US Preventive Services Task Force, "[The] variability in the composition of dietary supplements makes extrapolating results obtained from controlled clinical trials challenging."[81(p560)]

It is likely that at least some effect dilution may be associated with substantial variation in the actual concentration and bioavailability of active ingredients within and between manufacturers. Moreover, some harm associated with dietary supplementation may in part be attributed to heavy metal and other contaminants found in supplements, with larger doses naturally associated with greater toxicity. Without the necessary regulatory enforcement to ensure product quality and consistency, the preponderance of evidence collected on dietary supplements may be confounded by unmeasured variability in the supplements used and therefore lack validity; as such, the conclusion that dietary supplementation is not useful may be premature.

Conclusions

Dietary supplements are regulated in the United States by the FDA under the provisions of the DSHEA. Multiple challenges in regulatory enforcement have significant public health consequences, including inadequate evaluation of safety, insufficient requirements for efficacy, minimal surveillance for unsubstantiated labeling and marketing claims, poor quality assurance and control, and gaps in reporting of AEs in the context of a postmarket regulatory framework. Nevertheless, supplements continue to be used at a high rate because most consumers are uninformed about these issues. The US public is not well protected by existing laws, with the potential for harm from supplement use ranging from financial loss to serious adverse health consequences. Whether the public would be better served without the current regulatory system and the false sense of security it provides is questionable. ■

About the Author

Ranjani R. Starr, MPH, is with the Office of Public Health Studies, Department of Public Health Sciences, John A. Burns School of Medicine, University of Hawaii at Manoa, Honolulu.

Correspondence should be sent to Ranjani R. Starr, MPH, Office of Public Health Studies, Department of Public Health Sciences, John A. Burns School of Medicine, University of Hawaii at Manoa, Biomedical Sciences Building, Room D204, 1960 East-West Road, Honolulu, HI 96822 (e-mail: ranjani@hawaii.edu). Reprints can be ordered at http://www.ajph.org by clicking the "Reprints" link.

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Human Participant Protection

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Health Policy, Ethics, and the Kansas Legislative Health Academy

Erika Blacksher, PhD, Gina Maree, LSCSW, Suzanne Schrandt, JD, Chris Soderquist, Tim Steffensmeier, PhD, and Robert St. Peter, MD

We describe a unique program, the Kansas Legislative Health Academy, that brings together state legislators from across the political spectrum to build their capacity in advancing policies that can improve the health of Kansans.

To that end, the academy helps legislators develop new skills to deliberate the ethics of health policy, use systems thinking to understand the long- and short-term effects of policy action and inaction, and engage in acts of civic leadership. The academy also seeks to foster an environment of respectful open dialogue and to build new cross-chamber and cross-party relationships.

Among the most important outcomes cited by program participants is the value of sustained, personal interaction and problem solving with individuals holding differing political views. (*Am J Public Health.* 2015;105: 485–489. doi:10.2105/AJPH.2014.302333)

HEALTH POLICY OFTEN ELICITS controversy. Recent examples include the uproar over recommendations for mammography screening for women 40 to 49 years old and human papillomavirus vaccination for adolescent girls and boys. Perhaps the most dramatic controversy relates to the passage of the Patient Protection and Affordable Care Act (Pub L No. 111-148); despite being signed into law in 2010 and found substantially constitutional by the US Supreme Court in 2012 (Medicaid expansion was made optional for states), this legislation remains subject to vigorous dissent. Such controversies, although no doubt a function of interest-driven politics, also reflect deep differences in ethical values.

Ethical values and premises underpin all public policy.[1,2] Ideas about individual liberty, personal responsibility, solidarity, justice, and the role of the government are just a few of the moral constructs that often clash in the making of policy. Policy analysis often ignores these dimensions of policy-making, although that is beginning to change.[3–5]

Here we describe a project based in part on the premise that training policymakers to recognize and talk openly about the ethical values entailed in health policy might improve its content and process. This project, the Kansas Legislative Health Academy (hereafter Health Academy), brought together state legislators from across the political spectrum to build their capacity to respond to complex health policy challenges in Kansas. To that end, the curriculum sought to help legislators develop new skills in 3 areas: health policy ethics, systems thinking, and civic leadership. The Health Academy also sought to foster an environment of open, respectful dialogue and to build new cross-chamber and cross-party relationships.

To our knowledge, the Health Academy is a unique program. Many educational programs exist for legislators to focus on leadership development or specific health policy issues, but none we are aware of are specifically designed to cover a broad range of health policy issues while also addressing underlying barriers to effective policy-making within legislative bodies. In what follows, we describe the Health Academy's origins, structure, substance, and lessons learned.

ORIGINS

In Kansas, state legislators are part time, lack personal staff, share a small legislative research department responsible for all policy issues, and, as with other state legislatures, operate in a context of increasing political polarization. In addition, they face the sheer complexity of health policy, an aging population, and unsustainable increases in health care spending. It is in this context, in 2007, that conversations began among leaders of the Kansas Health Institute (KHI), the Kansas Health Foundation, and the Kansas Leadership Center (KLC), as well as several legislators, about creating an educational program to address barriers to effective policy-making. In 2009, the Kansas Health Foundation awarded KHI a grant of almost $323 000 to develop, implement, and conduct a program that would include 2 cohorts over 3 years (2009 to 2011). KHI also made substantial in-kind contributions, primarily in the form of staff time.

KHI undertook 2 preliminary activities prior to program development. Because participants