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USING COST-EFFECTIVENESS AND COST-BENEFIT ANALYSIS TO EVALUATE PUBLIC HEALTH LAWS

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A Methods Monograph for the Center for Public Health Law Research Temple University Beasley School of Law

OCTOBER 2023

MECHANISMS OF LEGAL EFFECT: USING COST-EFFECTIVENESS AND COST-BENEFIT ANALYSIS TO EVALUATE PUBLIC HEALTH LAWS

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Learning Objectives

- Understand the value of economic evaluations.
- Identify specific steps involved in conducting a careful economic evaluation.
- Understand the unique complexities and considerations when conducting an economic evaluation of an intervention targeting population health versus an intervention targeting individuals with a health problem or specific disease.
- Identify a strong research design for cost-benefit analysis (CBA) or cost-effectiveness analysis (CEA) focused on evaluating public health law from a societal perspective.

Economics is the study of markets and other mechanisms used to efficiently allocate society's scarce resources to their most valued purpose. Economic evaluation, which is an analytic framework for identifying the most efficient approach to achieving a stated objective, involves the identification, measurement, valuation, and comparison of the true economic costs and consequences of two or more interventions, programs or policies seeking to achieve that objective. While methods for conducting economic evaluations of targeted health care interventions (new medical devices, prescription drugs, or therapeutic approaches) have existed for several decades (Drummond & Stoddard, 1985; Gold, Siegel, Russel, & Weinstein, 1996), standards for conducting economic evaluations of more macro interventions targeting population-level objectives have only more recently been the focus of research groups and government agencies (Crowley et al., 2018; Levin et al., 2017; Moore, 2020; National Academy of Science, Engineering and Medicine [NASEM], 2016; Yates, 2018). This is due in part to the tremendous growth in the scientific tools and

applications of cost-effectiveness and cost-benefit analysis, the two most common forms of economic evaluation, applied in the evaluation of population-level interventions.

Unlike evaluations done in the private sector, where the focus is on return on investment to the private firm or individual, economic evaluations of policies and initiatives for a community focus on return to the community as a whole. This population-wide focus fundamentally changes how one measures both the costs incurred and the outcomes or benefits experienced. For example, while many medical and/or health interventions target specific patients with particular acute or chronic diseases, public health laws and interventions target a whole population or community, and often permanently change structures and practices in ways that affect not only the targeted population in the current generation but future generations as well. There are unique challenges to doing these types of evaluations, which have led many public agencies (NASEM, 2016; NICE, 2014), and even classic textbooks on the conduct of economic evaluations (Drummond et al., 2015; Levin et al., 2017), to develop new standards for evaluating "social interventions" and public policies aimed at the population level.

The goal of this chapter is to introduce the reader to current methods used in the conduct of a careful economic evaluation of public health law effects on population health. It outlines specific steps involved in conducting a proper analysis and the different choices made when dealing with issues at each step. I highlight that even when best practices are used, variability in the final calculation of cost effectiveness or net benefit often remain due to different underlying assumptions that an analyst might reasonably make within a given study. I present ways in which this uncertainty can and should be communicated to a decision maker. An educated consumer of these analyses will need to understand the relevance of this uncertainty in terms of implications for the reliability of recommendations based on cost-effectiveness or cost-benefit analyses. While this chapter provides an overview of the recommended steps for cost-effectiveness and cost-benefit analysis, as well as key issues that have to be considered within each, the interested reader is encouraged to dive into the additional resources referenced at the end of this chapter to gain a greater understanding of the many details I can only touch on here.

Steps in Conducting a Proper Economic Evaluation When Assessing a Public Health Law

Public and scientific organizations have only just begun defining their preferred standards for conducting economic evaluations of social interventions and refinements of these have already occurred (Wilkinson et al., 2019, 2016; Drummond et al., 2015; NICE, 2014). Nonetheless, there are certain common principles that have already emerged that are consistently recommended when conducting a scientifically rigorous, high-quality evaluation targeting a population-level outcome. I begin by breaking down the activities involved in conducting an economic evaluation, presenting

them as nine basic steps, and highlight current best practices for approaches and methods in each step for evaluating a public health law in particular.

STEP 1: DEFINE THE PUBLIC HEALTH LAW BEING EVALUATED AS WELL AS RELEVANT ALTERNATIVES.

While this is a seemingly obvious first step, it is in many instances given inadequate attention. While many public health policies involve the same terms, such as "legalization," "payment reform" or "eligibility," the laws referred to by these terms can differ dramatically. For example, the term "medical marijuana law" has been used to describe a wide range of laws that may: (1) prohibit any legal supply system, (2) allow for only home cultivation or private cooperative growing groups, or (3) allow for retail stores that may sell to any patient providing proper verification. Using the same term to describe these very different supply mechanisms is improper as well as confusing, and generates conflicting research from analysts who try to evaluate effects of these laws on specific outcomes such as teenage access (Pacula, Powell, Heaton, & Sevigny, 2015). A guide produced by the National Academy of Sciences, Engineering and Medicine (NASEM) (2016), explains that a clear statement of the purpose of the law requires a statement of the law's goals or objectives, the intended target population or recipients of the benefits of the law as well as the intended payers of costs, the intensity and/or duration of the initiative developed by the law, the scale of benefits/costs, and specifics related to its context. While this recommendation is helpful, it misses the subtlety that someone who is not an expert in the policy area may not understand how small deviations in the law (e.g. different supply mechanisms for of medical cannabis) influence the policy's objective or impacts. That's why the Society for Prevention Research takes this recommendation a step farther and recommends that the description of the law be detailed enough that readers who are not experts in the policy area can easily understand the essential elements of what is being considered as part of the policy, particularly elements of the law that describe the mechanisms through which behavioral change is expected to occur (Crowley et al., 2018). In short, economic evaluation research, like any evaluation research on a law, has as a foundation not only the specifics of the legal texts, but also a theory-based conceptual model of the purpose of the law, its intended targets, mechanisms and pathways of effect, and expected institutional and behavioral changes resulting from the law.

In addition to a clear description of the policy of interest (in terms of the precise elements of that policy that are believed to be important for affecting population health), it is important to thoroughly describe what the full set of alternative policy options are that the targeted policy is being evaluated against. This full set of alternative policy options might be quite large when CBA or CEA is being used prior to policy adoption (i.e. "ex-ante") because a thorough analysis would consider the full range of possibilities, not just the few most likely candidates. The set of policy options are typically smaller when conducting CEA or CBA post policy adoption (i.e. "ex-post"). At a minimum, and regardless of whether the economic evaluation is being done ex-ante or ex-post, one of the policy alternatives that should be included is the "status quo" (which may mean the absence of a policy or the continuation of an existing policy). The policy alternatives might also include

alternative laws or seemingly minor variants of the main policy being proposed. This is the subtlety that I was referencing above in the case of medical cannabis laws, where the policy options considered are those with different supply mechanisms.

Comparing the status quo just to the specific law adopted or of interest is too restrictive if the decision makers have other options available, because economic evaluations will only identify the most efficient allocation of society's scarce resources when all possible options are considered. Clearly articulating what that full set of alternatives actually is can be challenging, so many analysts in practice simply focus on the options that appear to be most feasible given the political and/or social environment.

STEP 2: ARTICULATE THE QUESTION BEING ADDRESSED BY THE ECONOMIC EVALUATION.

Just as it is important to clearly articulate the specific public health law being considered, as well as its alternatives, so too is it important to clearly articulate the question being considered in the economic evaluation being conducted. The specifics of the question being asked will determine what information is required to answer it.

For example, an economic evaluation considering effects of legalizing cannabis for recreational purposes on adolescent use of cannabis would focus on a very different set of outcomes, costs, and benefits than an economic evaluation that evaluated effects of legalization on adult use. The former would require information on youth initiation, escalation, use of different products and modes of administration, and risks associated with unexpected or long term exposure given the scientific evidence of harmful effects of cannabis on brain development (Hall, Leung and Lynskey, 2020). The latter would require information on adult use, intensity and duration, use of different products, and a more nuanced discussion of both the beneficial and harmful effects of occasional, regular, and chronic use of different formulated products, as not all use has been shown to be harmful (Hall and Lynskey, 2020). From a population health and societal perspective, neither of these studies would be adequate to fully consider the effect of cannabis legalization, as adults and youth are just particular subsets of the entire population affected by the change in policy. However, if the question is posed too narrowly, focusing on only one of these two population segments, then a full consideration of costs and benefits will not be undertaken.

Similarly, an economic evaluation that asks about the effects of Medicaid expansion on health care access would involve a different set of outcomes and data than an economic evaluation that asks about the effects of Medicaid expansion on health. The former would focus on the ability to obtain any health care services (e.g. primary care services, mental health services or addiction services), perhaps distinguishing access to clinically appropriate care from any health care service, while the latter would emphasize effects on health outcomes, including possibly mortality (Gruber & Sommers, 2017). From a population health perspective, it is how insurance influences health that is of greatest interest, and that might be missed if the focus is just on health care access. Thus, it is important to consider the question being asked in the economic evaluation to understand whether

the output from it provides sufficient information to fully evaluate the policy, in terms of outcomes, costs and benefits at the population level.

STEP 3: CLEARLY IDENTIFY THE PERSPECTIVE TO BE TAKEN.

Common perspectives taken when conducting economic evaluations of health laws include: (1) program or agency perspective, (2) recipients' perspective, (3) payer (usually government) perspective, and (4) societal perspective. Depending on the perspective taken in the evaluation, not all stakeholders' costs, benefits and outcomes are considered. The stated perspective also influences valuation of the resources used to achieve an outcome (a point I will return to in Step 6). When considering health laws, the most appropriate perspective is the societal perspective. Nonetheless, narrower perspectives are still used, often because they are easier or more feasible to conduct given time and resource constraints. These narrower perspectives limit the outcomes, benefits and costs considered and therefore can have important implications for the ultimate recommendation that comes from the study, not unlike the framing of the question. These distinctions in perspectives and how they shrink or expand what is considered in the analysis are perhaps best demonstrated through an example.

Let's consider an analyst conducting an economic evaluation of the effects of the ACA's Medicaid expansion on health care utilization of low-income individuals. An economic evaluation of the impact of the ACA on health care utilization conducted from just a program or agency perspective would consider those costs, benefits and outcomes that are most relevant to the agency/program and its implementation of the policy. These would likely include the administrative cost of expanding and managing new enrollees, the costs of health care utilization of newly covered individuals, and whether enrollees shifted utilization from high cost (emergency) care to lower cost (preventative care) services (Gruber and Sommers, 2017). The agency perspective might also include some effects on the newly insured (i.e. the recipients), such as improved access to a primary care provider and/or management of chronic health conditions, if the question being asked in the evaluation includes effects on access and health. However, an evaluation using only the agency or program perspective would ignore many other beneficial effects experienced by the newly insured, such as lower out-of-pocket expenses, reduced medical debt, reduced travel time to a health care provider, and/or reduced stress associated with medical issues (Finkelstein, Hendren, & Luttmer, 2019; Finkelstein, Taubman, Wright, et al., 2012). These are costs that are solely experienced by the recipient and are frequently not tied to an agency's objective in implementing the policy.

An evaluation that fully considers the recipient perspective (in this case potential Medicaid enrollees) would consider all the financial, physical health, mental health and time effects associated with this new coverage experienced by those gaining coverage under this policy, but would ignore the potential spillover effects this coverage might have in terms of the cost of insurance and/or healthcare received by the commercially insured, higher taxes paid by taxpayers to cover the agency cost of providing the additional health care services, or the effects of expanded patient loads on health care providers (Gruber and Sommers, 2017). The program recipient

perspective, therefore, focuses on the costs, benefits and outcomes experienced by the population targeted by the program or policy, not necessarily all those affected. It is increasingly common for analysts conducting economic evaluations of health care interventions today to account for both agency and patient perspectives, but accounting for the full range of population-wide societal benefits and costs remains extremely rare.

When considering a policy targeting population-level outcomes, most guidelines suggest an even broader perspective then the health agency + patient/recipient perspective (Boardman and Vining, 2017; Crowley et al., 2018; Drummond et al., 2015; NASEM, 2016). While the taxpayer perspective is at times confused with the agency perspective, it is actually broader in that it considers the allocation of the taxpayer's dollars across different government agencies, not just within a single agency. Any single agency is going to be focused on achieving the goals and objectives of that agency (e.g. health, education or criminal justice), while the taxpayer is ultimately concerned about the objectives and goals of all the government agencies they fund. So, in the example of the ACA Medicaid expansion, consideration of any possible labor market productivity gains associated with insurance coverage, which have the benefit to government of reducing welfare need and/or increasing tax revenue through employment, would be a non-health agency outcome that someone taking the taxpayer perspective would consider if the question is posed generally enough to allow it (Gruber & Sommers, 2017).

The broadest perspective, and generally recommended as the gold standard when conducting economic evaluations involving society's resources, is the societal perspective. The societal perspective considers not just the taxpayers paying for the policy implementation or the direct targets of a public health law (e.g., drunk drivers, smokers, Medicaid recipients, vaccination programs), but all members of a society that might be indirectly affected by a policy's adoption, including children, the elderly, immigrants and refugees. Depending on the policy, the societal perspective might include future generations who are not yet born but affected by a policy because of health gains achieved by policies implemented today (e.g., maternal nutrition programs, Medicaid expansion, clean indoor air laws). Given this much broader orientation, the societal perspective is difficult to fully implement in practice. It requires a complete accounting and measurement of costs and benefits to all members of a society directly and indirectly affected by a policy, as well as full consideration of spillover effects (both positive and negative) caused by these policies, in both the short and long run. Health laws, just like many other social policies, often influence multiple domains of our economy and society, including education and work productivity (Grossman, 1972; 2000). Thus, investments in health have many additional effects on society besides extending life expectancy, reducing disease and disability rates, and improving quality of life, and the gains can be sustained across generations (Robertson & O'Brien, 2018; Thompson, 2014). Trying to quantify all these effects and their net costs and benefits on the current population as well as future populations requires extensive data typically not readily available. In addition to identifying which costs, benefits and outcomes to consider in an evaluation, the specification of

perspective for the economic evaluation identifies *how* those values should be measured, a point that will be discussed in greater detail in Step 6 below.

STEP 4: IDENTIFY THE TYPE OF ECONOMIC EVALUATION TO CONDUCT.

As noted by Yates (2018), the absence of an established, unified standard for conducting economic evaluations of public health interventions has meant that various methods have been employed in the literature so far, including cost-minimization analysis, cost-consequence analysis, economic-impact analysis, cost-benefit analysis, cost-effectiveness analysis, cost-utility analysis and social return on investment (Drummond, O'Brien, Stoddart, & Torrence, 1998; Drummond, Sculpher, Claxton, Stoddart, & Torrance, 2015; Yates & Marra 2017). Any one of these methods might be used to consider a law's effects from an agency, recipient, government or societal perspective (Step 3), and all of these require an estimate of the *causal effect* of the intervention on its intended outcome (described in Step 7). The decision regarding which method to use ultimately depends on the question being asked and the available information to answer the question posed. The three primary approaches that have been widely used to evaluate health policies or compare health options to other social policy options are cost-effectiveness analysis, cost-utility analysis (a specific type of cost-effectiveness), and cost-benefit analysis.

Cost-Effectiveness Analysis (CEA) is an analytic framework for evaluating the desirability of a specific intervention over a set of alternative options by assessing and comparing each option's cost and effectiveness from the same stakeholder perspective, but where effectiveness is measured by a singular outcome of interest. In CEA, results are summarized through a cost-effectiveness ratio, where the numerator captures the net costs (total cost minus any cost savings of the intervention) and the denominator is the outcome measured in its natural unit (e.g. lives saved, illness averted, vaccines administered, and so on). An average CEA calculated in this manner can then be compared across a number of interventions of common duration to identify the intervention that has the lowest cost per unit of outcome. When comparing policy options of different duration, it is more common to construct an incremental cost-effectiveness ratio (ICER), which allows one to assess the incremental difference in net present value of costs (C) of two or more interventions per unit of effect (E) on the outcome, and is commonly represented (in the case of two interventions A and B) as:

$$ICER_{A,B} = \frac{C_A - C_B}{E_A - E_B}$$

Multiple interventions can then be compared in terms of their incremental cost effectiveness relative *to the same* baseline scenario (e.g. comparing all the options to option B, for example), enabling a more appropriate basis for comparison of a diverse set of interventions that have varying costs and levels of effectiveness over different time periods.

Cost-utility analysis is a special type of CEA where the outcome being examined is a multi-dimensional measure of health or wellbeing such as Quality Adjusted Life Year (QALY) or Disability

Adjusted Life Years (DALY). (Drummond et al., 2017). Construction of these multi-dimensional measures involves a description of health /wellbeing and a valuation of each health state. A variety of preferred methods have been developed to elicit population-based measures of wellbeing, including the Health Utilities Index, the EuroQol 5-dimensional questionnaire (EQ-5D), and the Quality of Well-Being Index. However, the bulk of this development has focused on evaluations in health, which is why cost-utility analysis has become the dominate and recommended form of CEA employed when evaluating most health interventions. Outside of health, critics of cost utility analysis argue that the complexities and assumptions needed to construct these measures of social well-being are just as numerous and problematic as cost benefit analysis, which has been broadly applied to evaluate a wide range of policies outside of health.

Most public health laws influence several health outcomes simultaneously, in addition to outcomes beyond health (Payne et al., 2013; Weatherly et al., 2009; Kelly et al., 2005). Cannabis legalization, for example, has been shown to reduce criminal justice expenditures (Caulkins et al., 2015) and have short-run positive effects on employment for some individuals (Ghimire & Maclean, 2020; Nicholas & Maclean, 2019), while also negatively influencing educational attainment (Chu & Gershenson, 2018; Marie & Zölitz, 2017) and health (Hall & Lynskey, 2020). It is very difficult within the CEA framework to develop a composite measure that captures these very disparate, but important, outcomes. Nonetheless, a true societal perspective requires consideration of each of them. This is why cost-benefit analysis remains a common tool for evaluating social policies, particularly when a broader taxpayer or societal perspective is taken in the analysis.

Cost Benefit Analysis (CBA) is an analytic framework for evaluating the social desirability of a program, policy or intervention in terms of its ability to improve efficiency over an alternative set of choices being considered, but mindful of all the alternative uses of those funds. It stems from welfare economics and has at its core the principal of maximizing efficiency, with the recognition that society's resources are scarce (limited) and hence any resources dedicated to the provision of one set of services are no longer available to be used on other valued services (Boadway 1974; Dasgupta & Pearce, 1972; Vining & Weimer, 2006). CBA is a tool that allows one to choose not just whether a particular health policy is the most effective way of achieving a health objective, but whether the use of those funds necessary to achieve the health objective is preferred to alternative non-health objectives the resources might also be used for.

Unlike CEA, where effects of an intervention or law are aggregated to a singular outcome measure (e.g. disease averted, lives saved, QALYs gained), CBA monetizes the value of all effects on outcomes (i.e. converts all effects to dollars gained or lost), which enables one to consider relative effects on outcomes originally measured in different natural units. The monetization occurs through a set of established techniques that include both revealed preference approaches (which base value from observed market behavior) or stated preference approaches (which acquire values through survey responses to hypothetical situations). The focus in CBA is on calculating the net benefit of policy option A over policy option B, where net benefits are calculated as the difference

between the present discounted value of benefits of Policy A over Policy B and the present discounted value of their costs. At times, analysts have constructed benefit-cost ratios, which generate a reduced form estimate of the benefit per unit of cost (again using present discounted value of both). The problem with benefit-cost ratios is that the magnitude of the benefits and costs become hidden. For example, a benefit cost ratio of 3:1 regarding Medicaid expansion might reflect a $300 return per $100 cost per Medicaid enrollee, or a $30,000 return per $10,000 cost. Such magnitude order differences are important for policymakers to consider, which is why net benefit calculations are generally preferred.

There are two primary criticisms of CBA. First, many health agencies and organizations are uncomfortable with the monetization of all outcomes, which require assumptions that are generally not agreed upon either among economists or others (Drummond et al., 2015; Marsh et al., 2012; Vining & Weimer, 2010; Viscusi & Aldy, 2003; Viscusi & Masterman, 2017). Ultimately, attaching a dollar value to outcomes depends on philosophical values – obvious when attaching dollar values to a person's life or years of ill-health. Second, CBA requires a thorough accounting of all potential effects, intended or unintended, beneficial or harmful, which are typically not known with certainty or reliability, especially when the CBA is being conducted prior to policy adoption. Given this difficulty, it is not uncommon for investigators to assess the sensitivity of findings by conducting a primary analysis in terms of a singular outcome using CEA or a subset of outcomes that are easily identifiable in a limited CBA, and then conducting a secondary extended analysis considering some, albeit not all, intended and unintended consequences using a CBA framework (e.g. Karoly, 2012; Kilmer, Burgdorf, D'amico, Miles, & Tucker, 2011; Kilmer, Caulkins, Pacula, MacCoun, & Reuter, 2010; Weimer & Vining, 2009; Caulkins et al., 2002).

STEP 5: DETERMINE TIME HORIZON AND DISCOUNT RATE.

Some public health laws stay in effect for decades (e.g. minimum legal drinking ages, prohibition of drugs, taxes on cigarettes), while others are short-lived. Thus, identifying the proper time horizon for costs, benefits and outcomes is complicated, particularly when analysis is being done ex-ante and the duration of the policy is uncertain. Moreover, timing of when costs and benefits occur may differ across legal options under consideration. In some instances, cost of implementing a law is paid immediately or in close proximity to the adoption of the law, while benefits (or unintended consequences) often accrue for years and even generations later. In other instances, the cost of a law (e.g. to legalize cannabis) is sustained over a long period of time, particularly if the law involves maintaining a new regulatory infrastructure (e.g. regulation of cannabis products and retail outlets). While often not achieved, the goal is a time horizon long enough to encompass all identifiable economic benefits and costs likely to accrue from the intervention (Office of Management and Budget, 2003).

In legal epidemiology, specifying a time horizon for CEA or CBA can be difficult for at three reasons. First, actual implementation of a law may happen immediately or might take years, or both when implementation requires incremental steps and stages. For example, legalization of adult-use

cannabis in multiple states has led to the immediate removal of criminal penalties for possession and/or use of cannabis, but the much slower development of regulations on cannabis products and retail outlets. Second, effects of the law on institutions and behaviors may be immediate (e.g. revenue from taxation of cannabis sold) or evolve more slowly (effects on low-birth-weight babies associated with cannabis use during pregnancy, or increased rates of vomiting and psychosis caused by higher potency products coming on the market). Third, short-run effects may not be indicative of longer-term effects, particularly when a law might stay in effect for generations. A careful evaluator selects a time horizon that ensures the public health intervention has sufficient time to: (1) be fully implemented, (2) affect the targeted recipients for a sufficient amount of time to reach a steady-state effectiveness rate, and (3) affect the general population for a sufficient amount of time such that spillover effects or unintended consequences are realized.

Importantly, as time horizon grows, so does uncertainty regarding the sustainability of policy implementation and magnitude of effects on the population's health (Basu & Maciejewski, 2019; Vining & Weimer, 2010). This is where simulation modeling, which can test alternative assumptions regarding rates of decay of effects of the policy on behavior over time, can be helpful. Considerable advancements have been made in the development of population-level single disease and multi-disease simulations. Such simulations consider progression of not just a particular disease on health but also their effects on productivity and income.

Discounting is a method for combining costs and benefits that occur at different times. It reflects both personal preferences and financial realities of markets. Goods and services received today are of greater value (when deemed desirable) than goods and services in the future, as most people are impatient and present-oriented and would prefer to consume them today. Moreover, if received today, they could be used and/or sold, with the proceeds earning a rate of return equal to the interest rate in the future. Thus, goods and services received today are of greater value than those in the future. Similarly costs that need to be paid out in the future have lower value today than their face value in the future because of the ability to earn a rate of return between now and then. Thus, discounting reflects these trade-offs of goods, services and income across time, including health (Claxton et al., 2019; Drummond et al., 2015).

There is general agreement that benefits and costs should be discounted at the same rate (Drummond et al., 2005; WHO, 2006), but not on what that rate should be when considering a social investment (Spackman, 2020). Economists usually use risk-free rate of return on savings, such as the return on US Treasury bills, as a measure of the discount rate. For an intervention generating costs and benefits that displace other investments in the economy, economists tend to rely on a market rate of return, or the opportunity cost of capital (Council of Economic Advisers [CEA], 2017). The precise values of these social discounts can depend on the country considering the policy. In the United States, the US Office of Management and Budget (OMB) has recommended that US agencies apply both a 3% discount rate and a 7% discount rate for a public good that benefits society, and then assess the sensitivity of findings to these rates (OMB, 2003). The US

Council of Economic Advisors (CEA) has suggested that these interest rates may be too high because of persistent declines over the past three decades in both the risk-free and long-term interest rates (CEA, 2017). Studies conducted in other, mostly European, nations following their own national guidelines use a lower range of values from 1.5% to 5% for studies with time horizons of at least three years (Haacker, Ballett & Atun, 2020).

STEP 6: IDENTIFY AND QUANTIFY OUTCOMES, COSTS AND BENEFITS.

Costing has two basic elements: (1) measure quantities of the resource used, and (2) assign the cost per unit (Drummond et al, 2015). There are challenges to both of these steps when examining policies at a population level, as not all resources involved in implementing a policy are easily identified or measured and assigning unit costs to those resources can be difficult. Tangible resources, such as personnel, supplies, technology and services, are the easiest to identify but can still create challenges for analysts assigning unit costs when market prices do not reflect the true opportunity cost of those resources. Intangible resources are particularly difficult to measure. The value of physically safe neighborhoods, for example, or the cost of pain and suffering from losing a loved one are difficult to measure. The value of intangible resources (lost life, feeling of safety and security) usually represent the largest share of total costs or benefits in an economic valuation, so their inclusion and method of calculation are important. A variety of methods have emerged to generate proxy prices for them, each with their own strengths and weaknesses (Boardman, Greenberg, Vining, & Weimer, 2011; Drummond et al, 2015).

Suppose we are analysts being asked to evaluate the economic benefit of a state's adoption of a law requiring physicians and pharmacists to access prescription drug records before prescribing or distributing opioids to patients, frequently referred to as must-access prescription drug monitoring programs (PDMP). The objective is to reduce overprescribing of prescription opioids, thereby reducing overall access to opioid prescriptions, and hence risk of overdose. Must-access PDMPs involve establishment of state-level electronic databases that collect information from pharmacies, hospitals, physician offices and other dispensers of pharmaceutical drugs on the controlled medications that are being distributed to each individual when they fill their prescriptions. These data are then made available to authorized users, usually doctors and other prescribers, for the purpose of learning about their patients' full history in filling prescriptions of interest before making additional prescriptions. In 43 states, law enforcement agencies also have access to these electronic databases, to monitor patients who may be seeking drugs by pharmacy and/or doctor shopping, as well as identify prescribers who may be improperly prescribing opioids or other controlled substances. Imagine we are told by the state's health department that they want to know what effect this must-access policy has had on opioid prescriptions per capita in the state – they hope to see a reduction – and how many lives it has saved from fatal opioid overdoses. We know the policy was adopted five years ago and fully implemented three years ago.

The example thus far provides a clear description of the question being asked and the law being evaluated. What is unclear is the perspective that should be taken and the time period for which

this should be evaluated. Both affect the costs, benefits and outcomes. Without such clarity, we start the exercise with a list of resources we can think will be used due to the adoption of the law, based on our knowledge of the scientific literature examining previously adopted PDMP laws. With this list, we can then check back with the state (our client) to make sure we have in fact considered all the costs they think are relevant. Table 16.1 provides a snippet of that list, describing first in broad categories the type of resources that we know the literature has already considered: health care resources, patient/family resources, and some other non-health care community resources. Concrete examples of specific community resources in each of these broad categories are shown in each row. Because the state did not specify what perspective we should take in conducting our analysis (health care agency + patient perspective or societal perspective), and because we know that the societal perspective is the recommended perspective when conducting an economic evaluation of a public health law due to its use of society's limited resources (Drummond et al., 2015; Vining & Weimer, 2009), we construct our list of resources using both perspectives so we can share insights using each with our client.

Table 1: Identifying and Valuing A Partial List of Costs and Cost-Savings Associated with a State Must-Access Prescription Drug Monitoring Program

	Examples of Costs Included in Category	Valuation of Cost from Health Care Agency + Patient (HCA+P) Perspective	Valuation of Costs from Societal Perspective
Health care resources (costs and potential cost savings)			
Technology implementation	Purchase of hardware and software technology enabling the remote access, lookup and importantion of data into PDMP system across different health systems/ IT platforms in a manner meeting HIPAA requirements	Market prices associated with the IT hardware, software, and installation services to get the system functioning, storage capacity (server) for the database, and enhanced cyber security. Rent for facility storing database	Same
IT support & maintenance costs	Labor providing software, hardware IT and network support as well as technology costs to meet security requirements	Market prices for IT support, software updates, server maintenance, and cyber security	Same
Provider / pharmacist training	Develop training materials and implement training	Wages for labor and and market prices for materials/travel necessary to develop and deliver training either in person or virtually	Same
Provider / pharmacy monitoring	Labor & software materials needed to ensure use by all providers / pharmacists	Programmer and management time and wages, market prices of resources used to verify utilization by prescribers/distributors	HCA+P cost plus any potential positive/negative spillovers monitoring has for medical malpractice litigation
Regulating agency responsibilities	Board or health agency responsible for conducting surveillance of over prescribers & implementation of penalties; and coordinate with law enforcement	Programmer and management time and wages, analyst time and wages to identify and report suspicious behavior as indicated by data	HCA+P cost plus potential negative/positive spill over effects this surveillance & monitoring has on prescribers / pharmacies practices
Treatment utilization associated with opioid misuse (cost savings)	Cost of treating patients with an opioid addiction (inpatient/outpatient detox, behavioral therapy, and/or medication assisted therapy)	Therapist and staff time and wages for scheduling, intake, therapeutic plan development, and delivery of therapy, rental rate of space where therapy takes place for time of therapy	HCA+P cost plus spillover effects (positive or negative) this change in treatment utilization has on access to treatment by other patients in need of treatment
Other non-addiction treatment health care services	Averted or new opioid-involved non-overdose ED visits, outpatient visits, complications caused by opioid-using pregnant women; NICU cost of opioid-dependent newborns plus cost (or cost savings) associated with non-opioid treatment of pain	Insurance-negotiated price of labor, diagnostics, therapies, facility fees, and prescriptions averted due to reduction in prescription opioids + saved out of pocket cost of patients	HCA+P cost plus any rise in health care service use caused by shift to other opioids (heroin, fentanyl) or non-opioid therapies outside of the health care system
Cost of responding to overdose (cost savings)	ER, hospital, and ambulance service providers time and capacity costs	Insurance-negotiated prices of labor, diagnosistics, therapies for medical and first responding staff to manage averted Rx opioid overdose	HCA+P cost plus spillover effects due to increased / reduced capacity of ED and first responders on respond quickly and care for other emergency patients
Patient/ Family resources (cost and potential cost savings)			
Extra hassle created for patients to find docs willing to prescribe opioids	Time costs, transportation costs, hassle of finding new provider, family caregiving while time is spent seeking new care	Wages for lost time and caregiving costs, market rates for transportation/parking/tolls, proxy value for stress/hassle	HCA+P cost plus spillover costs on family members or friends who assist patient in these efforts or cover at home/child care to facilitate search
Increased or decreased functionality and productivity associated with change in opioid prescriptions	Ability to do activities of daily living and/or other activities that could be managed either because opioids provided relief from pain or because opioid addiction impaired functionality	Proxy value for functionality of patient	HCA+P cost plus additional cost / cost savings associated with family members/friends who had to assist patient either due to non-treated chronic pain or addiction
Increased or decreased risk of addiction associated with lower access to Rx opioids	Savings/costs from new opioid dependent patients due to either lower initiation of Rx opioids , or switch to more potent illicit opioids	Proxy value of cost of living with addiction	HCA+P cost plus additional proxy value for emotional cost/ cost savings of family members/friends who are affected by patient
Increased or decreased risk in opioid related mortality	Costs or savings associated with rise/fall in opioid related mortality	Proxy value for lost/saved life from opioid overdose	Proxy value of pain and suffering of those who lost/saved the loved one, foster care placements (caused by overdose of a parent).

Table 1 (Continued): Identifying and Valuing A Partial List of Costs and Cost-Savings Associated with a State Must-Access Prescription Drug Monitoring Program			
	Examples of Costs Included in Category	Valuation of Cost from Health Care Agency + Patient (HCA+P) Perspective	Valuation of Costs from Societal Perspective
Non-health care community costs			
(1) Law Enforcement costs			
Surveillance of patients seeking meds thru doctor shopping / pharmacy shopping	Labor & software materials needed to set up monitoring algorithms in data, investigate potential suspects	Not considered	Market wages and prices of software and supplies related to monitoring plus proxy price for the opportunity cost of law enforcement time spent allocated to this versus other policing activities
Surveillance of and actions related to over-prescribers	Labor & software materials needed to set up monitoring algorithms in data, investigate potential suspects, coordinate with health agency	Not considered	Market wages and prices of software and supplies related to monitoring plus proxy price for the opportunity cost of law enforcement time spent allocated to this versus other policing activities
Spillover of patients to black market seeking access to medications there (Alpert et al, 2018)	Labor & investigative resources to monitor and intervene strategically in local illicit market, track domestic/international supply chain, deal with rising drug-related arrests	Not considered	Market wages,, market cost of surveillance resources for local and federal law enforcement who track and investigate illicit markets, time spent processing new drug arrests, plus proxy value for the opportunity cost of law enforcement time spent allocated to this task versus other policing activities
(2) Neighborhood/community costs			
Rise in illicit markets related to reduced access through medical sector (Alpert et al, 2018)	Marginal impacts of growth in illicit market on community safety, cohesion, and economic opportunities	Not considered	In addition to law enforcement costs mentioned above, there are impacts on employment choices of community members (legal or illicit job market and implied trajectories), risk of crime generated by drug markets and overall neighborhood safety, which have to be measured using proxy values
Impact on Emergency First responders system (Pike et al., 2019)	Marginal impacts on EMT and ambulance resources associated with change in fatal overdoses	To the extent that these are paid for by the health care system, they are included above. Any community resources (e.g. fire, police, 9-1-1- lines, and community groups) would be added here	HCA+P costs plus any spilloer effects on community agencies (fire, police, community volunteers) due to increase/decrease in opioid related 9-1-1 calls
Impact on social welfare related to infants and children of parents misusing opioids (Feder et al., 2019)	Marginal impacts on social services, foster care, and other agencies who manage children who are in the care of an individual struggling with addiction	Not considered	Market value of labor time and resources used in conducting social service activities (monitoring, evaluation, placement) in addition to proxy value on children for lost of parent
Potential impact on disability and labor markets (Maclean et al., 2021)	Marginal impacts on labor market supply, employment, productivity	Not considered	Proxy value for changes in rates of unemployment, lost/gained wages due to reduced productivity of opioid users, lost/gain tax revenue

Table 16.1. Identifying and Valuding A Partial List of Costs and Cost-Savings Associated with a State Must-Access Prescription Drug Monitoring Program.

Let's try to describe a bit more carefully what some of the actual resources are that we want to measure and cost for this exercise. Within the health care system, the implementation of a must-access PDMP requires information technology (IT) infrastructure (hardware, software, networking systems allowing for remote access and real time updates) that can be assessable from both pharmacies and prescribers' offices. Greater use can be achieved by having this integrated into the prescribers' existing health system software, to avoid double entries and/or multiple look ups, but that could require new IT platforms that allow for communication about patient sensitive data in a manner that meets Health Information Portability and Accountability Act of 1996 (HIPAA) requirements. Ongoing IT support of the PDMP database created as well as the software and hardware supporting it will be required. Training may be required for all end users, and for those responsible for monitoring prescriptions and checking compliance. These are the most obvious tangible health care resources involved in implementing the PDMP system. If the system is effective in reducing unnecessary opioid prescribing and deterring misuse of opioids, then there will be additional outcomes that also affect the health care system and agency resources, such as a reduction (or possible increase) in the number of patients needing opioid addiction treatment, the

number of opioid-involved emergency department visits, complications caused by opioid-using pregnant women, and neonatal intensive care unit costs associated with fewer opioid-dependent babies. These changes, if realized within the time period being considered in the evaluation study, would represent resources saved within the health care system on account of the law as well as costs incurred responding to an opioid overdose (Table 16.1).

Must-access PDMPs will also influence patients, and possibly their family members. Exactly how depends on the policy's actual impacts (part of what the evaluation is designed to explore) as well as the time period over which they are considered. For example, some individuals who had been using the health care system to obtain prescription opioids for nonmedical use will now find it more difficult to obtain prescriptions from multiple physicians or fill them at multiple pharmacies, as this sort of doctor shopping and pharmacy shopping behavior is exactly what these PDMPs are designed to discourage. However, the oversight created by PDMPs has also caused some prescribers to be less willing to prescribe an opioid either because of the additional hassle of having to check the PDMP system before doing so (affecting new and existing patients) or because they do not want to trigger investigations into their medical practice by continuing to prescribe high doses of opioids to patients with chronic pain conditions. When comparable non-opioid therapies are available to address pain experienced by patients, this behavioral change by prescribers has no negative effect on patients aside from the time spent trying to find an alternative therapy that works. Moreover, it may lead to an overall societal net benefit as fewer people are at risk of becoming dependent on opioids when fewer opioids are being prescribed for pain. However, when comparable non-opioid therapies are not available to patients who have been using high dose opioids to manage chronic pain, this behavioral change by prescribers places an additional burden on patients who must now either look for a new provider who is willing to prescribe opioids in high doses or, if that is unsuccessful, find a nonmedical (illegal) supply. The time and hassle spent searching for these new therapies and sources of supply represent a real cost to the patient. Additionally, there may be lost functionality and/or productivity that occurs during this time. Those individuals who choose to turn to illegal sources of supply for opioids are now placed at greater risk of both addiction and unexpected overdose due to the unregulated products available through illegal markets.

An analysis of just the health care agency plus patient perspective would stop there. However, we know from the literature that a robust must-access PDMP policy will necessarily involve resources from law enforcement as well, because law enforcement agencies have primary responsibility for investigating and prosecuting individuals inappropriately seeking medications through the health care system. They may also be directed to investigate prescribers who appear to overprescribe medications for financial gain rather than patient welfare. To the extent that patients seek illicit sources for their medications first, and then cheaper opioid alternatives like heroin and fentanyl, the illicit market will grow requiring even more law enforcement resources to squash incoming supply. The presence of, and profits associated with, illicit markets can generate harms to

neighborhoods, by making them less safe. Neighborhoods become unsafe due to actions of both the illicit suppliers seeking to protect new territories as well as by the consumers, who due to their opioid use may become less attentive and engage in risky behaviors (leaving children unattended, engaging in fights, impaired driving, sharing needles, and so on). Regular or persistent consumers of high potency opioids are likely to become addicted, generating effects on the individual's family members (children, spouses, parents) who may rely on that individual for income, care giving, or emotional support. Those children who are no longer able to be cared for by the consumer are sent to relatives or the foster care system. These are just a few examples of non-health effects that research has already identified, but there is now enough variety in resources already mentioned to start thinking about the challenges of assigning unit prices to each.

Having identified various community resources affected by a must-access PDMP, we will need to consider the time period over which to evaluate these effects and costs. Given rates of opioid mortality are still rising exponentially, it would seem as though the targeted recipients (nonmedical users of opioids at risk of opioid fatality) have not yet reached a steady state in response to the law's adoption, so for the purposes of our hypothetical example, I would suggest we use at least a 10-year period, which would allow some of the spillover effects on the community to be felt and measured. Now, we are ready to start thinking about the costs of these resources.

As mentioned already, market-based valuations are frequently considered to be good approximations of the values of resources, particularly when markets are working efficiently on their own. In our example of the must-access PDMP policy, market prices for labor, hardware, software and supplies needed to build, operate and maintain the PDMP platform (hardware, software and network) as well as train people on it are all appropriate as these goods and services are all sold in highly competitive markets. There are other categories of resources shown in Table 16.1, however, for which market prices will not work for at least two reasons: (1) the market list price or price paid by the agency is not reflective of their true opportunity cost of those resources, and (2) the resources are not formally traded in markets (e.g. time spent looking for non-opioid therapies or alternative prescribers, feeling of safety in a neighborhood, value of a life lost due to an overdose).

In the case of health care, there is a pervasive problem that the list prices or charges that hospitals, physicians and even pharmaceutical companies charge for their products and services do not reflect their true opportunity cost. This is due to the fact that health care markets in the United States are not truly competitive; imperfect and asymmetric information coupled with high barriers to entry do not allow competition to drive prices down to the true social value of the inputs being used in production. So, using list charges or fees, which do not reflect the prices that insurance companies or other payers pay, would not appropriately capture their value as they include overhead costs (the cost of maintaining the hospital or ambulatory care building structure, or training residents) and the fixed/sunk costs of specific investments they already made (having extensive medical technology ready to use, or recovering costs from research and development of

new pharmaceuticals). So, when estimating the value of fewer (or greater) opioid treatment admissions in response to must-access PDMP adoption, as shown in Table 16.1, we only want to include the marginal cost of providing this treatment. To do this, we want to consider the time spent by an administrator involved in intaking a new patient, the therapist (or team of therapists) developing a therapeutic plan, and then the provider's time engaged in delivering that treatment. This can be constructed by considering the time of the providers and staff involved in these activities and their wages, not actual charges to patients. Similarly, when considering the cost to the health care system of responding to an overdose, we do not want to consider the price of the ambulance or firetruck responding to the overdose. Instead, it is the time and wages of the team responding to the call as well as any medical services used while treating the person in need. Costing these specific units involved in the delivery of care rather than average cost of delivering care to everyone served better captures the incremental cost of the resources being used for this law.

Table 16.1 also provides numerous examples of patient and non-health care system resources that are not actually traded in markets, such as the patient's time spent investigating alternative treatments or providers, the functionality patients gain through the appropriate use of prescription opioids and lose when these medications become unavailable to them, and the value of lives saved through avoided fatal overdoses. For these intangible effects, analysts typically use proxy prices which are obtained using one of three primary approaches: (1) *human capital*, which try to assess the added or lost value of the nonmarket good in terms of productive time, (2) *revealed preference*, which use real information conveyed in markets for related or similar goods and services, and (3) *stated preference*, which are methods that seek to elicit through surveys and hypothetical scenarios how a consumer values various nonmarket goods.

For a long time, economists have used the value of lost earnings in the marketplace, or the *human capital* approach, as the primary method for measuring the opportunity cost of time and nonmarket goods that are related to time, like a lost life. The basic premise for this approach is that the person's wage is a good measure of what the person is giving up by not working, so whenever the person chooses to not work and do something else instead, it clearly must be valued at least as much as the same time they could have spent at work. There are several limitations of this approach that have been discussed in the literature (Boardman, 2011; Drummond et al., 2015), but two are particularly important here. First, this approach ignores serious imperfections in labor markets which are known to exist. Look within any society and you will find subpopulations based on gender, race and ethnicity being paid differential amounts for the exact same work due to discrimination. Similarly, looking across jobs there are enormous inconsistencies in pay per value of the job. For example, entertainers and elite athletes get paid wages that far exceed those of school teachers, police and fire fighters, yet few would argue that these highly paid individuals are worth that much more to society. Second, the use of wages as a proxy price for the value of time

ignores the consumption value people place on their time. When we take time to make a meal from scratch with healthy ingredients, the value of the time spent cooking itself may be a pleasurable activity. The fact that pain medication enables a patient to work a productive workday is important and valuable, but only using a measure of the wage ignores the value that patient places on the additional pain-free time that medication allows them to have enjoyable activities at home with friends and family. In light of these two serious limitations, human capital methods have moved somewhat out of favor as a means of valuing nonmarket goods, although they are still used to value lost work time or productivity due to being sick or in pain.

Revealed preference approaches are those that attempt to use information revealed through existing markets for proxy goods (increased safety, lower risk of death) to infer the value of a range of nonmarket goods, including time and lost life. Given the range of nonmarket goods we need to price (e.g. stress/hassle of finding new therapies, functionality when experiencing less pain, safe neighborhoods, and value of lost life), it is perhaps not surprising that a wide variety of revealed preference approaches have emerged, including the market analogy method, intermediate good method, hedonic price method, travel cost methods and defensive expenditures method (Boardman, 2011). The validity of the estimates produced from any of these methods depends critically on that method's ability to isolate the unique value of the proxy good itself. For example, some studies have used differential housing values in high crime neighborhoods versus low crime neighborhoods as a way of valuing a safe neighborhood. In theory this would work great, except those other attributes of homes also influence their pricing across neighborhoods including proximity to a major freeway or jobs, noise, pollution, school districts, and proximity to green space or beaches. So, if the goal is to isolate the value placed on safety alone, the analyst must use methods that allow them to isolate the variation in housing associated with crime alone and not other factors.

The two main revealed preference approaches commonly used to estimate the value of lost life are (1) wage premium approach and (2) defensive expenditure approach. Both approaches assess the value of a lost life by calculating the extra income (expenditure) people receive (pay) to take on incrementally larger (smaller) risks. The wage premium approach uses information about risk premiums people receive for taking on different risks on the job for similar work, such as doing construction on skyscrapers versus working construction on one- or two-story buildings, as an indicator of the payment that must be received for greater risk of death. Because people have different preferences for risk and different abilities to assess risk, the values of a lost life obtained using this method can range widely, from $920,000 to $20 million (Hirth, Chernew, Miller, Fendrick, & Weissert, 2000). The defensive expenditure approach uses information on how much people pay in the marketplace for safety devices that produce small reductions in the risk of fatality to construct estimates of the value of lost life. Given the range of defensive purchases made (from bike helmets to safer cars) the range of estimates of the value of lost life using the defensive purchase methods also vary widely, from $770,000 to $9.9 million (Viscusi & Aldy, 2003). It is unclear to

what extent these large variances result because of variation in the quality of studies (i.e. the analyst doing a better/worse job controlling for other attributes that people like about these goods), the inability of the consumer to understand the change in risk associated with these purchases, or because the valuation of life differs based on number of years of life remaining.

Given the limitations and concerns of revealed preference approaches, alternative methods relying on *stated preferences* have emerged. The two most common stated preference methods are (1) contingent valuation (Mitchell & Carson, 2016; Arrow et al., 1993), where individuals are asked through surveys what they would be willing to pay (or be paid to avoid) a particular outcome (e.g. a reduction in risk of illness or death), contingent upon a hypothetical situation, and (2) discrete choice experiments (Green & Gerard, 2009; Ryan, Gerard, & Amaya-Amaya, 2008), where individuals are given a series of hypothetical scenarios that differ along very specific attributes related to the nonmarket good and, based on responses to these scenarios, a valuation can be calculated. There are several advantages of these methods over previous methods mentioned, particularly when trying to construct an estimate of the value of life, as they can be used to value mortality risks for which we have little reliable market analogs (e.g. cancer risk or terrorism attack), and they can be used to obtain estimates of valuations from children and elderly directly (who often have surrogates purchasing goods for them in the market place). However, these methods also have their limitations, in that they assume that people can reliably understand the implicit tradeoffs of the scenarios described, and accurately assess the likelihood of low and high probability events, which is a common error for many (Thaler & Sunstein, 2009). Moreover, there is evidence that people tend to undervalue hypothetical income or risks, a phenomenon known as "hypothetical bias" (Harrison & Rutström, 2008). Given these concerns, guidelines for the proper conduct of both of these approaches have been developed and continue to get refined, as improper implementation can lead to inconsistencies in valuations derived from these methods (Boyle, 2017; de Bekker-Grob, Ryan, & Gerard, 2012; Johnson et al., 2013; Lancsar & Louviere, 2008). Estimates of the value of a life using these methods also tend to be large, ranging from $100,000 to $25.9 million (Hirth et al., 2000).

Due to the tremendous variation in values for a lost life in the academic literature generated from these three approaches (human capital, revealed preference and stated preference), many government agencies use their own preferred proxy value when conducting studies (Viscusi, 2010). For example, the US Environmental Protection Agency uses $7.5 million (in 2006 dollars) as its recommended standard price for the value of a life saved or lost (EPA, 2012), the US Department of Transportation (DOT, 2016) uses a value of $9.6 million (in 2015 dollars), and until just recently when values were updated for inflation, the Department of Health and Human Services had been using an average value of $9 million (in 2013 dollars) (US HHS, 2021). These are not trivial differences, as few other costs or benefits considered on a per unit basis have variation in value in the millions. Thus, any analyst concerned about which proxy estimate for the value of lost or saved life to use should check the sensitivity of their result to alternative, reasonable values.

Even though we have not assigned actual prices or counted resources affected in our example, it is clear from Table 16.1 that an economic evaluation conducted from a societal perspective requires additional considerations of factors even if we only focus on counting health care system resources. This is because the societal perspective requires the consideration of unintended consequences associated with the must-access PDMP law that may result from its adoption. For example, the development of the must-access PDMP platform may assist plaintiffs (patients, health insurance companies, and other payers) seeking to sue providers or prescription drug companies for overprescribing of opioids, anti-psychotics, or other medications. Alternatively, the system might make certain providers or pharmacies willing to maintain opioid prescribing and dispensing routines targets of thieves seeking medications. Such spillover effects, which clearly affect certain health care actors although not in expected ways, would be considered when using the societal perspective, but not the health care agency and patient perspective. More importantly, the societal perspective considers effects on a wide range of agencies not directly affected by the PDMP law but involved in addressing the harms and implications of opioid misuse and fatalities, namely law enforcement agencies, extended family members, neighborhoods, and social services. The inclusion of these additional community resources that are utilized in response to changes in medical and nonmedical opioid use can dramatically influence the net impact of the PDMP on the state's resources.

Regardless of which perspective is taken, there are resources in Table 16.1 for which fairly reliable market prices are available (e.g. health IT costs, training costs) and then some intangible effects where there is likely to be pretty large ranges for valuations (e.g proxy value for functionality of the patient, living with addiction or lost/saved lives). Moreover, the exact number of units of each resource to count may be uncertain due to uncertainty associated with actual effects. For example, if more patients choose to seek alternative treatments in lieu of opioids, then the effects (in terms of resources) of must-access PDMPs on first responders would be less than if more patients decide to use illicit opioids. Similarly, if pregnant women or mothers of young children seek treatment rather than an alternative source of pain medications, there is less need for medical and social services. This sort of uncertainty of effects is not uncommon in many evaluations of social policies (Vining & Weimer, 2010) and is what makes cost-benefit and cost-effectiveness analysis particularly challenging. Recommendations on how to deal with these issues are discussed next in steps 7 and 8.

STEP 7: ASSESS EFFECTIVENESS OF ALL POLICY ALTERNATIVES BEING CONSIDERED.

Effectiveness estimates are typically obtained from original research conducted on small pilots, a randomized controlled trial (RCT), a natural experiment, and/or reviews and meta-analyses of existing findings from established literature. The reliability of information on effectiveness from these sources should still be assessed by the analyst in terms of its applicability to the specific evaluation being done. Reliability and applicability of previous effectiveness findings for the economic evaluation will depend on several factors, including representativeness of the sample that

was previously studied vis-à-vis the current population, specific effects considered, quality of the data used to estimate effects, and quality of the research designs used.

Studies evaluating policy candidates often rely on sample data that is not fully representative of the larger and more diverse population the law would eventually affect. One of the most prominent RCTs examining the effect of early preschool on poor, at-risk youth was the Perry Preschool experiment, conducted in the late 1960s on a sample of 123 African American children living in Michigan. While the experimental design and implementation of the study were technically strong and appropriate for the question being asked at the time, the generalizability of these findings for other at-risk youth populations in other settings and time periods has been appropriately questioned, leading to subsequent follow up studies using different populations and settings (Lally, Mangoine, & Honig, 1987; Masse & Barnett, 2002). The effectiveness of the policy is also a function of the targeted population's acceptance and responsiveness to the policy, which may differ from those observed in a pilot or RCT due to factors such as demographics, culture, attachment to institutions, and political philosophies. Finally, effects can differ across subpopulations due to differential implementation, enforcement and/or compliance due to cultural or social differences across populations. For more on RCTs in policy candidate and evaluation research, see Chapter 13.

Even if the population from which the effectiveness measure is drawn is similar to the population targeted by the policy being evaluated, the outcomes measured in the prior research might differ from those being considered in the economic evaluation. For example, an RCT might identify effects of a policy on health care utilization while the analyst doing an economic evaluation is concerned about effects of the policy on health outcomes or lost productivity. In such instances analysts connect findings from various studies to link policy effects on utilization to effects on health and productivity, for example. A more difficult problem for analysts is when studies only evaluate effects over a short period of time, say three, six or 12 months, when the analyst needs to incorporate longer term effects 10 or 20 years later. An analyst cannot simply assume that effects observed over short periods will hold for longer periods. There are too many factors that can change over time, including implementation, enforcement, compliance, and norms, that can cause an estimated effect to decay or grow over time. Analysts facing the problem of unmeasured long-term effects often have to make assumptions about the persistence of effects, using either mathematical function approximations or carefully modelled trajectories accounting for plausible shifts in factors that might influence persistence over time. Regardless of technique, recent guidelines related to the conduct of cost benefit analysis of social policies recommend using modeling techniques that consider multiple assumptions about decay or growth, rather than just one, to illustrate sensitivity of findings to the assumptions made (Crowley et al., 2018; Henrichson & Rinaldi, 2014; NASEM, 2016).

Assumptions regarding persistence of a policy effects are important, and often not given sufficient consideration. The current US opioid epidemic is a good reminder of the dangers of presuming a constant policy effect over time in a dynamic world. By all accounts, the opioid

epidemic began in the late 1990s and early 2000s by the overpromotion and excess prescribing of opioids, in particular OxyContin (Alpert, Evans, Lieber, & Powell, 2022). But by 2010, when states started implementing supply restrictions and OxyContin got reformulated to reduce the ability of consumers to crush and snort it, the opioid crisis shifted as consumers who had already become dependent on OxyContin moved to a cheaper, more potent substitute, heroin (Powell & Pacula, 2021; Powell et al., 2019). While PDMP laws were generally found to reduce opioid mortality for much of the early 2000s, after 2010 prescription opioids were no longer the primary driver of opioid mortality, heroin was (and then fentanyl). The effectiveness of PDMPs at reducing opioid drug overdoses, therefore, could not be presumed to be the same after 2010 as it was before 2010 (Kim, 2021).

Finally, data quality is important. Factors influencing the quality of data include the data generating process, the suppression of certain jurisdictions due to lack of reporting from them, and the extent to which the available data truly reflect the outcome of interest. Even widely-used, publicly provided data, such as the Centers for Disease Control National Vital Statistics Surveillance (NVSS) system, the Agency for Health Care Quality and Research Hospital Cost Utilization Program (HCUP) data, and the CMS Medicare/ Medicaid data have limitations or have undergone significant changes in data collection processes that influence the quality of the data for studying particular phenomena. Not all researchers are fully informed about these limitations and changes, which can cause them to use the data inappropriately.

In the case of the NVSS data, for example, it is now well-understood that systematic differences in the coding of opioid-involvement, overall and by type of opioid, existed on death certificates across states throughout the first decade of the opioid crisis. This systematic difference in coding occurred because some states use medical examiners (trained medical career professionals) to fill out death certificates while other states use coroners (politically appointed staffers) to do so (Davis & National Association of Medical Examiners and American College of Medical Toxicology Expert Panel on Evaluating and Reporting Opioid Deaths, 2013). The implication is that death certificates from states which use coroners are less likely to identify the specific type of opioid involved in a drug overdose, while states with medical examiners are more likely to record type of opioid involved when such information can be determined. The differential reporting of these data across states complicates analyses evaluating state PDMP policies on opioid-specific mortality rates (e.g. prescription opioid mortality, heroin mortality or synthetic opioid/fentanyl mortality) as some states get dropped entirely from these analyses because of data limitations despite having relevant laws in place. Researchers who are aware of this issue have developed imputation methods and supplemental analyses to verify the magnitude and direction of estimated policy effects (Ruhm 2017, 2016). But not all studies reflect awareness of data anomalies, which is why analysts need to consider data quality issues before using a study's measure of effectiveness in an economic evaluation.

STEP 8: CONDUCT SENSITIVITY ANALYSES, EXAMINE PRIMARY DRIVERS OF UNCERTAINTY.

Uncertainty is expected in any economic evaluation. Uncertainty arises from many sources, including uncertainty regarding the degree of implementation, enforcement or compliance with an adopted policy, uncertainty regarding estimates of effectiveness on outcomes from existing studies, uncertainty with respect to market valuations of benefits and costs (both now and in the future), uncertainty associated with forecast projection period, and uncertainty associated with models (data and parameters) used to determine presumed effectiveness of a policy on outcomes beyond those measured in the literature. A careful economic evaluation does not eliminate uncertainty, but succinctly and clearly articulates the extent to which this uncertainty matters for decision-making by end users of the economic evaluation.

Best practice includes additional supplementary analyses (referred to as "sensitivity analyses") of estimated cost-effectiveness or net benefit for comparison with "base case" estimates. Base case estimates are those that are calculated using the preferred values of all the variables and assumptions: estimate of effectiveness, value of benefits and costs, preferred discount rate, preferred projection of future trends, and so on. Sensitivity analyses are conducted by using alternative plausible values of variables and modeling assumptions (Crowley et al., 2018; Drummond et al., 2015; Briggs, Sculpher, & Buxton, 1994). The alternative values are usually easy to find. Most published studies evaluating effectiveness of a given policy will report not just the average effect of a policy on an outcome but also the 95% confidence interval. Similarly, it is often possible to obtain lower and upper bound estimates of specific valuations of costs and benefits to capture the heterogeneity in values that might be relevant (e.g. if there is population heterogeneity). Model parameter uncertainty can similarly be considered by rerunning the model with alternative values of specific parameters for which a plausible range of values are likely to exist, testing the sensitivity of the model results to these different parameter values (Briggs et al., 1994). Testing the sensitivity of the base case calculation of cost-effectiveness or cost-benefit to alternative sources of uncertainty clarifies how robust the results are.

Two approaches are used when conducting sensitivity analyses: univariate sensitivity analysis and multivariate sensitivity analyses. The approach depends on the analyst's certainty regarding values used in the base case, which is a function of the quality of the work generating those values. When there are relatively few factors for which the analyst is uncertain and those uncertain factors are not interdependent, then the analyst will usually adopt a univariate approach, sometimes referred to as a partial or one-way sensitivity analysis (NASEM, 2016; Drummond et al., 2015). Implementation of this approach is easy in that the analyst simply conducts the same analysis over and over again, each time varying the single parameter of interest within the pre-specified range of values, holding all the other estimates and values at their baseline case values. Univariate sensitivity analysis, when done iteratively for all potentially uncertain values in a calculation, is useful for identifying which parameter or parameters are key in generating uncertainty about the value of the overall calculation. Many economic evaluations will generate what is known as a tornado graph to demonstrate the sensitivity of the final net benefit or cost effectiveness calculation to alternative plausible model assumptions. Figure 16.1 is an illustration of a tornado graph

assuming the median net benefit calculation of our hypothetical PDMP policy discussed in Step 6 is $1.5 million. Each row in the tornado graph shows the impact on that positive net benefit calculation of changing a single parameter used in the baseline estimate, holding all other parameter values constant at the baseline value.

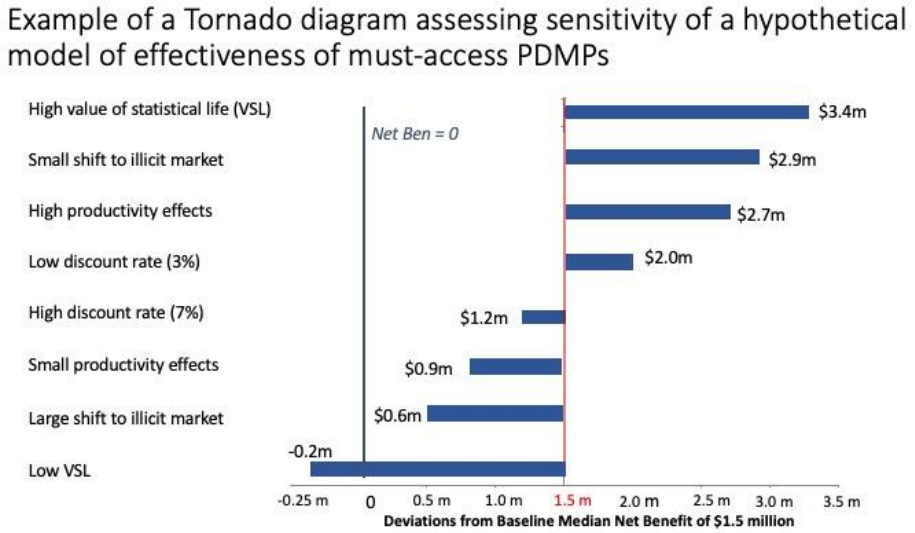

Figure 16.1. Example of a Tornado Diagram Assessing Sensitivity of a Hypothetical Model of Effectiveness of Must-Access PDMPs.

Bars to the right of $1.5 million show that the calculation becomes even more positive than the baseline calculation, while bars to the left show that the calculation becomes less positive. It is not until we assume the lowest value for a statistical life that the net benefit calculation is no longer positive. Thus, this tornado graph conveys to the analyst and decision maker that only one of our uncertain underlying assumptions changes the overall conclusion of the study, although the uncertainty definitely influences the magnitude of that net gain.

The univariate sensitivity approach ignores associations between parameters, that is, their covariance. For example, the size of the shift of consumers to the illicit market is likely to be correlated with lost productivity time in addition to the number of individuals who die from an illicit fentanyl. Monte Carlo methods, which involve repeatedly sampling parameter values from a pre-determined range for all uncertain parameters simultaneously and allowing for joint distributional assumptions across parameter values, allows the analyst to construct an estimate of the variance around the calculated estimate of net benefit or cost-effectiveness in a manner that considers simultaneous changes in multiple parameters. Because multivariate sensitivity analyses comprehensively consider the various types of uncertainty, it is the recommended approach (Crowley et al., 2018; OMB, 2003; NASEM, 2016; Vining & Weimer, 2010). The larger the number of samples drawn through the Monte Carlo methods the more reliable the estimate of the variance; thus, typically simulations are repeated tens of thousands of times. Results of Monte Carlo simulations (e.g. 10,000 trials) can then be plotted using histograms, which show the share of trials

for which a particular value of the net benefit or cost-effectiveness ratio emerge, illustrated in Figure 16.2 for our hypothetical assessment of the net benefits of must- access PDMPs.

In CBA, analysts typically summarize uncertainty using the proportion of Monte Carlo trials conducted that yield a positive net benefit calculation, because only policies with a positive net benefit would be recommended (NASEM, 2016; Washington State Institute for Public Policy, 2015; Vining & Weimer, 2010). If the proportion of trials generating a positive net benefit is large, for example 86% in the hypothetical presented in Figure 16.2, then the analyst can be reasonably comfortable that under a range of scenarios the policy will generate a net benefit. However, it is still useful to convey to the decision maker that there are scenarios where the net benefit could be negative. As the proportion of positive net benefit calculations moves further away from 100%, the relative certainty of a societal gain with adoption of the policy decreases.

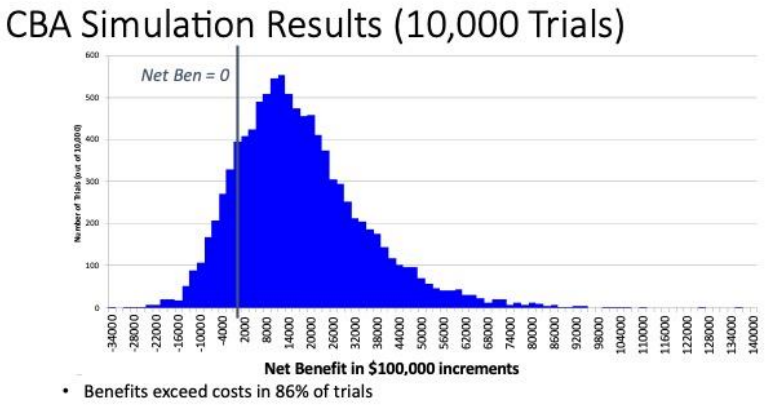

Figure 16.2. CBA Monte Carlo Simulation Results (10,000 Trials).

Similar methods exist for conveying uncertainty around a single incremental cost effectiveness value (Boardman et al, 2017; Polsky, Glick, Willke, & Schulman, 1997). However, when conducting CEA, there usually is not always a single target value that analysts are trying to reach. Given the uncertainty in both the underlying assumptions of the CEA construction as well as the threshold values of interest, cost effectiveness acceptability curves have become a common tool for conveying uncertainty when CEA is used. The cost effectiveness acceptability curve summarizes in a single graph the uncertainty associated with any single CEA calculation as well as the threshold value that any particular CEA may be trying to achieve. As shown in Figure 16.3, the cost effectiveness acceptability curve shows the percent of Monte Carlo simulation runs accounting for uncertainty generating cost-effectiveness ratios exceeding different threshold values of willingness to pay (specified in terms of $ per QALY).

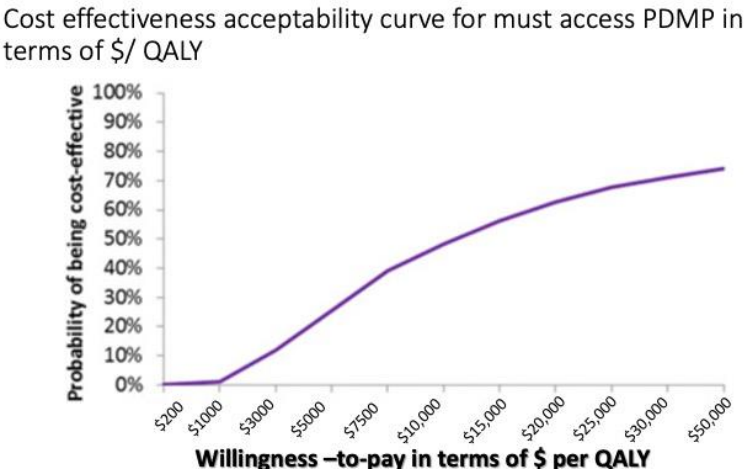

Figure 16.3. Cost Effectiveness Acceptability Curve for Must Access PDMP in Terms of $/QALY.

One aspect of uncertainty that is often overlooked is the role of benefits/costs that could not be valued in the exercise, either because they involve nonmarket goods for which valuations are highly contested (e.g. the value of a statistical life, or loss of child during pregnancy) or because evidence on potential spillover effects has not yet been produced, even if such spillover effects are possible (e.g. the extent to which pain patients decide to seek pain medications through illicit markets rather than seek non-opioid therapies within the medical system. Several examples of these were offered in Table 16.2 where the valuation of costs and benefits for a must-access PDMP were considered. In work with my colleagues at RAND, we would refer to these uncertain but potentially important effects as "wild cards" (Caulkins et al., 2015; Kilmer et al., 2010). While it is not possible to explicitly include them in the economic evaluation, the circumstances under which these unknown factors can switch the final calculation from positive to negative is something that should be conveyed to decision makers if known.

STEP 9: APPLY DECISION RULE CRITERIA UNDER ALL PLAUSIBLE UNCERTAINTY FROM STEP 8 AND CLEARLY REPORT RESULTS.

Depending on the question being asked and the type of economic evaluation undertaken, different summary measures can be generated, and whether a law is a good investment will depend on the summary measure used. For CBA, net benefit and benefit-cost ratios are the most common summary measures employed, but occasionally internal rates of return and return on investment are also used. When using net benefit as the primary decision rule, the reference decision point may be a net benefit > 0, if comparing a policy to the status quo, or it may be a minimal positive value if comparing across policies. As noted previously, benefit-cost ratios might also be used, with any value greater than 1 indicating more benefit to costs (some have also reported cost-benefit ratios, where a ratio < 1 would indicate higher benefit per dollar of cost), but these ratios hide information about the relative magnitude of the benefits and costs vis-à-vis other options that might also be considered, which may also be useful information to the decision makers. For CEA, summary

measures include cost-effectiveness ratios or incremental cost-effectiveness ratios for the cost per outcome gained, where the outcome measure can vary from narrow outcomes, such as infection rates, disease rates, or hospitalizations averted, to more comprehensive measures, such as quality- or disability-adjusted life years.

Regardless of the method and measure used, it is critical to clearly communicate the results of the evaluation in a manner that enables understanding of the findings for a broad audience, particularly policy makers (NASEM, 2016). To do this, the study must adhere to a strong principle of transparency, but do so in a manner that does not overwhelm the decision maker with too much information. While several recent guidelines recommend summary tables that provide details of the values of all parameters used in the construction of a base case estimate, the sources used for these effect sizes and valuations, as well as the range of values assessed to address underlying uncertainty (NASEM, 2016; Henrichson & Rinaldi, 2014; ISPOR Task Force, 2013), it is also important to communicate clearly to the reader those parameters and values that create the greatest chance of flipping a decision. When findings of cost-effectiveness or net cost benefit are sensitive to reasonable assumptions others could make, those specific assumptions should be conveyed clearly. Similarly, if there are certain assumptions that can cause the decision to switch from being beneficial to being harmful, those assumptions should be made explicit. While it may be difficult to know with certainty the exact value of parameters that cause these decisions to turn, it may still be possible to convey an understanding of the range of parameters that generate one outcome versus another.

Including measures that summarize the overall uncertainty regarding the metrics used are also recommended. In CBA, analysts typically use the proportion of Monte Carlo trials conducted that yield a positive net benefit calculation as a measure of uncertainty, because only policies with a positive net benefit would be advised (NASEM, 2016; Vining & Weimer, 2010). If the proportion of trials generating a positive net benefit is large, for example 86% in the hypothetical simulation presented in Figure 16.2, then the analyst can be reasonably comfortable that under a range of scenarios the policy will generate a net benefit. However, it is still recommended that the analyst convey to the decision maker what specific scenarios will cause the net benefit calculation to become negative (or fall below a prerequisite value), so they are able to consider for themselves the potential risk of a bad outcome. In CEA, if the government agency or policy maker has a firm perspective of a threshold value of willingness to pay per unit gain, then the analyst can simply report the probability of the policy being cost effective at that specific threshold, but again it is useful to describe what values in the calculation increase the risk of it not being cost effective at that value. More often, in light of uncertainty regarding the preferred threshold value of willingness to pay, analysts are encouraged to present an entire cost effectiveness acceptability curve to enable the decision maker to see the likelihood of an intervention being cost-effective at different presumed levels of willingness to pay.

The purpose of CBA and CEA is to assess efficiency – identifying which laws generate the highest societal value given the resources involved in achieving them. Equity is not a consideration. The ultimate metric of these economic evaluations is still based on the net overall outcome, not an even or fair distribution of benefits and costs. Equity should be a genuine concern for decision makers, so conveying information about the distribution of gains and losses across stakeholders and subpopulations is also useful. Indeed, recent guidelines recommend subpopulation analyses of particularly vulnerable populations, so that the potential inequities generated or exacerbated by a policy might be considered (Wilkinson et al., 2016; WHO, 2006).

Additional issues for quality economic evaluations of public health law

Basic principles of economic evaluations are much easier to apply in narrow settings where a particular treatment or intervention is applied to a relatively small homogeneous group. A law almost always applies to an entire community or state, creating considerable additional complexities beyond those discussed here (Vining & Weimer, 2010). These include a divergence in valuations caused by differences in status within the community, the limitations of using willingness to pay as a basis for social preference ordering and valuation, and the uncertainty regarding total causal effects of laws, due to interacting causal pathways and feedback loops that exist in our complex society.

A core principle of an economic evaluation is that an average value of a resource, determined by the community through markets or other methods, is a meaningful measure. However, people within a jurisdiction can have substantial differences in these values, particularly when non-market goods (time, sense of belonging and security, healthy functioning of the community) are translated into dollar values. The value that someone places on any particular dimension of health reflects not just their individual preferences for that good but also their position in society--where they are in status hierarchies. Most analysts are trained to obtain an average or other measure of central tendency in obtaining values across these different populations, as this is deemed the proper way of capturing value across the full population (e.g. median income, average cost of health care). However, using averages masks important information about equity. Given evidence of growing disparities in health and in the social determinants of health (Chetty et al., 2016c; National Center for Health Statistics, 2016), analyzing subpopulation valuations of both costs and benefits is important. Moreover, some laws are explicitly designed to achieve distributional goals related to health and well-being, not maximize efficiency. The field is far from a consensus on how best to present tradeoffs between efficiency and equity using economic evaluation methods.

A standard neoclassical assumptions underlying economic evaluations is that willingness to pay, as reflected by market demand curves, represent the true social value of the good to society. However, this assumption may not hold in diverse populations, particularly when large segments of the population do not engage in a given market due to disagreement with the use of resources to that purpose (e.g. diesel fuel in cars, plastic bottles containing water, and so on). This assumption

only holds when preferences are transitive (Sen, 1969; Arrow, 1963). Preferences are said to be transitive when their ordering is preserved no matter what comparisons are made. If a person prefers option A to option B, and option B to option C, then transitive preferences mean that they will prefer option A to option C. But, even if individual preferences meet the condition of transitivity, in the aggregate as a population the assumption might not hold. While some subpopulations might prefer option A to option B and option B to option C, other segments might prefer option C to option A. In aggregate, depending on the relative sizes of groups with different preference orderings, the transitive preference assumption could easily be violated. This disrupts any agreement on what the "best" policy approach would be for the full population. It also disrupts the assumption that willingness to pay, as reflected by market valuations of the costs, benefits and outcomes associated with that policy, are indeed an accurate assessment of society's valuation of the resources involved. When segments of society remove themselves from a marketplace, in protest regarding the market, then accurate inferences of willingness to pay cannot be presumed.

A final consideration when conducting economic evaluations of public health laws specifically is the extent to which a study considers all the potentially relevant effects associated with an adoption of a policy, however uncertain. The fact that an outcome is unlikely does not mean it will not come to fruition, as we unfortunately learned with the reformulation of Oxycontin in 2010 (Powell & Pacula, 2021). Regulators presumably understood that the approval and marketing of an opioid formulation labeled as less subject to abuse would lead to much wider medical use, but evidently did not anticipate or discounted the possibility that wider medical use would ultimately lead to such a large-scale change in the illicit market for opioid medications, which brought with it a rise in hepatitis C and fatal overdoses caused by heroin and then fentanyl (Alpert et al., 2018; Powell, Alpert, & Pacula, 2019; Powell & Pacula, 2021). Even well intended and well-designed policies can generate negative outcomes in light of the diverse communities and circumstances in which people live, work and play. An awareness of this potential, particularly in areas beyond health, is important to keep in mind when considering public policies.

Concluding thoughts

Economic evaluation of a law requires more than just applying a societal perspective when assessing costs and benefits. It requires a serious consideration of all stakeholders, which for public health includes all individuals present in the jurisdiction with the law. The broad range of intended and unintended consequences associated with a law must be included, both in the short term and the longer run. Accounting for multiple beneficial and deleterious population outcomes is difficult, and projecting potential effects into the uncertain future is even more so. Nonetheless, new tools and methods continue to emerge improving economic evaluations and better revealing the uncertainties inherent in them. High quality economic evaluations will keep this broad perspective in mind as it related to outcomes, omitted populations, and valuations, even if the question being

asked by decision makers is perhaps too narrowly focused on just the items that can be readily assigned dollar values with current measures and methods.

When conducting analyses of public health laws in particular, it is important to keep in mind that the majority of societies are far from homogeneous in their populations. People within the same jurisdiction live in different circumstances, face different daily stresses, have different cultural or religious values, and start with different baseline levels of health, income and education. Any population-wide public health policy that is implemented will result in a variety of social outcomes, costs and benefits, given this underlying heterogeneity. While an economic analysis can do a good job of identifying whether a policy on net might be cost effective, it is important to consider the extent to which those who do not benefit from a law, or are possibly harmed by it, might be compensated. Well intended laws, such as drug prohibitions, have resulted in extremely large costs imposed on particular segments of society. Law frequently addresses actions of institutions and behaviors of persons that are the result of complex social phenomenon, but they address them at times using blunt sticks (mandates or prohibitions). Consideration of the economic, social, and welfare effects beyond health is important and requires the use of outcome measures that captures these dimensions. But consideration of who incurs the outcomes, the costs and benefits, is also important when evaluating the desirability of a law or policy. When economic analyses are comprehensive and done well, they can provide insights into who the winners and losers are, but the decision rule typically does not explicitly consider equity. Equity must still be considered by the analyst in the formulation of the policy analysis in the first place, or by the decision maker after the fact.

Further Reading

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