Asymmetric Assessments in Valuing Pharmaceutical Risks

W. Kip Viscusi, PhD,* Wesley A. Magat, PhD,† and Robert Scharff, BA‡

Key words: Food and Drug Administration; pharmaceutical risk assessment; risk assessment; risk, responses to. (Med Care 1996;34:DS34–DS47)

Economic critics of the Food and Drug Administration (FDA) have long noted the substantial asymmetry between how different risk effects of pharmaceutical products are handled. In particular, the agency acts as if its objective is to minimize type II errors, where the risk being averted is the chance that a defective new drug will be approved. Thus, FDA officials are concerned with avoiding approval of drugs such as thalidomide, which led to birth defects in England but was never approved for use in the United States. Receiving much less attention are the type I errors, which are the risks that could have been averted had drugs been approved earlier. The drug approval process in Europe, for example, is much faster than in the United States. Important new drugs, such as beta blockers, which are valuable in treating patients with heart disease, reached the market in the United States long after they had been in use in Europe. As a result, many lives were lost that could have been saved had this drug been available earlier.

In the usual government regulatory choice, the trade-offs to be considered are between benefits and costs, where the benefits are comprised of risks averted and the costs consist of dollars. In the case of pharmaceutical regulation, the main trade-off is between two different kinds of risks. Pharmaceutical products present intrinsically life and death issues. The principal benefit associated with the products is the reduced risks that result when they are effective, but a principal class of costs is associated with the presence of possible adverse health effects. To date, the FDA has placed greater weight on the risks of adverse health effects than on the risk reduction benefits so that these classes of risks are treated asymmetrically.

An important exception has been with respect to drugs for well-identified constituent groups. The acquired immunodeficiency syndrome (AIDS) lobby, for example, has been successful in leading the FDA to expedite the approval process for AIDS-related drugs. In many instances, however, the group that will benefit from the drug is not a well-identified group and, consequently, will not be able to mount an effective lobbying campaign. In such instances, the potential type II errors typically will receive a much greater weight than the type I errors because the beneficiary population is more diffuse.

Some of the drugs that satisfy the criteria of being either type I or type II errors appear in Table 1. In many instances, drugs had been improved in Europe before they had
been approved in the United States, thus making it possible for these patients to avail themselves of beneficial new drugs. Table 1 lists a number of such drugs that were approved for use in the United Kingdom before the United States. Although these drugs provide examples of beneficial new products that could have been made available sooner in the United States with a more expeditious review process, one danger of a less careful review is that drugs will be put on the market too soon and will create adverse effects. The errors of commission avoided by the FDA are summarized for a half dozen instances of drugs that were used elsewhere, but were not approved in the United States. One of the most famous instance of an adverse reaction is that of thalidomide, this case is by no means unique. Thus, the government faces a difficult task of balancing the two classes of competing risks associated with any pharmaceutical product.

<table>
<thead>
<tr>
<th>Table 1. Examples of Type I and Type II Errors in New Drug Approvals</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>A. Type I Errors Made by US Food and Drug Administration</strong></td>
</tr>
<tr>
<td><strong>Safe Drugs</strong></td>
</tr>
<tr>
<td>Beclomethasone dipropionate</td>
</tr>
<tr>
<td>Sodium valproate</td>
</tr>
<tr>
<td>Cimetidine</td>
</tr>
<tr>
<td>Protirelin</td>
</tr>
<tr>
<td>Somatotropin</td>
</tr>
<tr>
<td>Phospholipids</td>
</tr>
<tr>
<td>Danazol</td>
</tr>
<tr>
<td>Disopyramide phosphate</td>
</tr>
<tr>
<td>Propranolol</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>B. Type II Errors Avoided</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Unsafe Drugs</strong></td>
</tr>
<tr>
<td>Practolol (United Kingdom, 1969)</td>
</tr>
<tr>
<td>Medihaler-Iso Forte (stronger form of isoproterenol than approved in the United States)</td>
</tr>
<tr>
<td>Aminorex (Switzerland, 1965)</td>
</tr>
<tr>
<td>Ibufenac (United Kingdom, 1966)</td>
</tr>
<tr>
<td>Benziodarone</td>
</tr>
<tr>
<td>Thalidomide (United Kingdom, 1959)</td>
</tr>
</tbody>
</table>


This asymmetry in the response to errors of omission and errors of commission is not limited to the FDA. Individuals, as well, display a similar kind of asymmetry in their responses to risk. Increases in risk often are treated differently than decreases in risk in terms of their evaluation. This article explores the character of these different variations. In addition, it examines how this asymmetry in response affects the appropriate valuations that should be attached to the health outcomes involved. This article explores the nature of the biases characterizing individual decisions involving risk, as well as the consequences of these biases for the valuation of health outcomes associated with pharmaceutical products.

The first section of this article will review the different types of asymmetric responses to risk. Some of these asymmetries are legitimate economic responses that reflect rational discrepancies between the valuations of an increase or a decrease in risk. In other instances, however, these biases are not rational in the context of standard economic models, but instead stem from failure to process the risk information accurately or to respond to it in a sensible fashion. This article reviews the various inadequacies that have been identified in the literature. The second section explores the consequences of the asymmetry for the valuation of health outcomes and presents specific examples of such valuations. In the third section, the implications of this asymmetry for survey design are explored. In particular, how should surveys of individual health outcome valuations be structured so as to eliminate the potential biases that arise from the various irrationality effects? The fourth section concludes the article.

**Types of Asymmetric Responses to Risk**

Consider a new drug that offers a decreased risk of mortality of 1/100,000. Suppose the drug has no other adverse affects and that the only concern is how much individuals value the decreased risk of death. More specifically, suppose that they all view this decreased mortality risk as being worth $50. This would be a "willingness-to-pay" amount for a reduced risk.

Now consider a second drug that has a benefit of substantially decreasing morbidity, but has the adverse side effect of imposing an increased mortality risk of 1/100,000. How should we value the economic loss experienced because of the increased risk of death be valued? This amount would be a "willingness-to-accept" amount, or the amount of money that individuals must be compensated to accept an increase in risk. Is this value also $50?

In situations in which the willingness-to-pay amount equals the willingness-to-accept amount, the valuations will be identical. One can then use them interchangeably. In theory, this will be the case if there are sufficiently small changes in the risk involved. However, for larger changes there may be a discrepancy. Moreover, if one were to survey individuals regarding their attitudes toward these different risk contexts, then one would likely find a substantial spread between the willingness-to-accept amount and the willingness-to-pay amount. In general, the willingness-to-accept value will exceed the willingness to pay value. Put somewhat differently, people will be more reluctant to incur an increase in the risks they face than they will be to spend money to achieve an equivalent risk decrease. In this section we will explore why this difference arises, what legitimate economic factors may account for it, and what behavioral anomalies have been observed that generate these patterns.

**Rational Economic Models**

Even in the context of the usual economic model in which people are behaving fully rationally, there may, in fact, be a discrepancy between the willingness-to-pay and willingness-to-accept values. The first rea-
son is that of income effects. Consider a hypothetical example in which an individual has the opportunity to purchase successive reductions in risk incrementally. One such instance would be that in which the individual is forced to play Russian roulette and there is the opportunity to purchase successive bullets from the gun to decrease the potential risk of death. In general, the willingness to pay to purchase bullets back will be a decreasing amount per bullet. One reason for this is that each purchase of a bullet from the gun makes you successively poorer. Because the valuation of health status typically declines with income levels, one will consequently observe a lower willingness to pay for risk reduction as one’s resources are depleted.

An analogous principle applies as the risk is increased. As one faces successive increases in risk for which one is compensated, one’s wealth will increase. Because health becomes more valuable as one becomes more affluent, the amount of money required for additional increases in risk will rise as one receives additional compensation for these risk increases. Thus, there is a discrepancy as the willingness-to-accept measure per unit risk will exceed the willingness-to-pay measure per unit risk. This result is general for any risk increase or risk decrease and can be attributed to what are known as income effects.

There also may be a discrepancy arising between willingness to accept and willingness to pay because of substitution effects. In particular, when there are no perfect substitutes available, the willingness-to-accept amount will tend to exceed the willingness-to-pay amount. Pharmaceutical products that are unique in terms of their health consequences lead consumers to require more compensation (willingness to accept) to be willing to have these products removed from the market than if there are readily available substitutes.

Irrational Behavior and Valuation Asymmetries

Although there may be legitimate economic reasons why individuals may express a higher value for their willingness to accept an increase in risk than their willingness to pay for a decrease in risk, in many instances these discrepancies are stark—too great to be explained by rational differences in valuation. A large number of cognitive theories have emerged to address different reasons why such discrepancies in stated values arise.

Table 2 summarizes the large number of cognitive explanations that can be used to explain the discrepancy between willingness-to-accept and willingness-to-pay values. Although seven different explanations will be distinguished, the differences among these explanations often are not great. For example, status quo bias, endowment effects, and omission effects reflect very similar phenomena. In contrast, some of the influences, such as regret avoidance and

---

*Although the following discussion will be with respect to a hypothetical example involving risk, this principle is more general. In particular, the willingness-to-accept value (or the compensating variation) equals the willingness-to-pay value (or what is called the “equivalent variation”) plus an income effect. This is a standard result in public finance and is discussed in Willig and Freeman.

†Another reason for the diminished valuations of risk as the number of bullets in the gun declines is that money has a higher opportunity cost as one purchases successive bullets from the gun. A decrease in the number of bullets implies that there is a lower probability of death and consequently a higher probability that one would have been alive and able to spend the money after participating in Russian roulette. This difference will make money more valuable and consequently less willing to spend money to reduce risk as the number of bullets decline.

‡Willig has shown that for small variations income, willingness to accept is close to willingness to pay.

§More specifically, the willingness to accept or compensating variation equals the willingness to pay or equivalent variation plus an income effect plus a substitution effect. (See Hanemann and Shogren.)
certainty effects, will prove to be quite distinctive in character.

The first possible explanation for the asymmetry between willingness to pay and willingness to accept stems from some of the rationales put forth in prospect theory, which is an analysis of choice under uncertainty articulated by psychologists Kahnemann and Tverksy.6

In prospect theory, the discrepancy between willingness to pay and willingness to accept arises for two reasons. First, individuals exhibit loss aversion. In particular, individuals are highly averse to situations in which there will be a decline in their current income status. One potentially could generalize this to pertain to changes in health status. Individuals similarly should be reluctant to engage in situations that may lead to a degradation of their health.

A second component of prospect theory, which has been documented in the literature on risk perception more generally,7 is that individuals place a premium on situations involving zero risk. It is noteworthy, for example, that the FDA does not declare products to be acceptably risky, such as posing a risk of death to Americans of one in ten million. Not to say, for example, that bacterial contamination of meat has been reduced so that only 10 Americans will die from it next year would be unacceptable. Rather, the agency stresses that food and pharmaceutical products have been made “safe,” without indicating the specific magnitude of the risk present. In one notable instance, the Delaney clause that pertains to food additives, zero carcinogenic risk is the goal.

The impetus for this relation is that the magnitude of small risks may tend to be overestimated. An additional factor is that there may be less worry and concern about a risk knowing that it has been reduced to zero. In terms of the willingness to pay for a risk change that leads to a zero risk, individuals would be willing to pay more than is sensible based on the actual magnitude of the risk because they overestimate the extent of the risk improvement that is being achieved. Similarly, if a situation is encountered in which there is an increase in the risk from zero, they also will overestimate the

<table>
<thead>
<tr>
<th>Economic Explanations</th>
<th>Summary of Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Income effect</td>
<td>Valuation of goods is directly correlated with income and wealth.</td>
</tr>
<tr>
<td>2. Substitution effect</td>
<td>A premium is placed on goods with no close substitutes.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Cognitive Explanations</th>
<th>Summary of Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Loss aversion</td>
<td>Losses are valued at a higher level than gains.</td>
</tr>
<tr>
<td>2. Certainty effects</td>
<td>A premium is placed on certain outcomes.</td>
</tr>
<tr>
<td>3. Reference risk effects</td>
<td>Increases in risk from the current level are valued more than similar decreases in risk.</td>
</tr>
<tr>
<td>4. Status quo bias</td>
<td>There is a distinct preference for the current state of affairs.</td>
</tr>
<tr>
<td>5. Endowment effects</td>
<td>Ownership of a good or attribute increases its value.</td>
</tr>
<tr>
<td>6. Regret avoidance</td>
<td>Decisions that one may come to regret are avoided.</td>
</tr>
<tr>
<td>7. Omission effects</td>
<td>There is an exaggerated preference for inaction.</td>
</tr>
</tbody>
</table>
deterioration of safety involved and have a willingness-to-accept amount that exceeds the amount they would have had if they perceived the risk change accurately. These influences alone would not produce an asymmetry between the willingness-to-pay and willingness-to-accept amounts. However, to the extent that the risk increases in the willingness-to-accept context arise in situations that are viewed as currently zero risk (ie, a new risk is being created), and the willingness-to-pay situations involve those in which the risk is being diminished but not completely to zero, then there will be an asymmetry in which the willingness-to-accept amount will be greater.

Although this theory is suggestive, it does not predict a discrepancy between the willingness-to-pay and willingness-to-accept values for changes in risk. One theory that does this is Viscusi et al’s in what they term “reference risk effects.” In their theory, individuals are sensitive to the risk starting point. Risk increases that entail an increase in the probability of the adverse outcome will be viewed with alarm. As a consequence, the willingness-to-accept amount for a risk increase will be quite great. In contrast, there will be no such exaggerated response for risk decreases. Because decreases in risk are associated with the willingness-to-pay amount, this asymmetry will lead to an asymmetry in the valuation of changes in risk and a value of willingness to accept that often greatly exceeds the willingness-to-pay amount per unit risk even for very small changes in risk. The empirical properties of this phenomenon will be documented below.

There are two closely related theories that also suggest that individuals are particularly reluctant to incur adverse disturbances from their current situation. The first is the status quo bias theory of Samuelson and Zeckhauser, which shows that individuals have preferences for their current situation in a wide variety of contexts. This behavior is seen by the authors as resulting from rational decision making in the presence of transitions costs and/or uncertainty, cognitive misperceptions, and psychological commitment stemming from misperceived sunk costs, regret avoidance, or a desire for consistency.

One such context examined is that of health insurance. When faced with a set of alternative plans from which to choose, individuals anchored upon their current choice more than would be predicted based on a rational assessment of plan differences. This result was derived by looking at data from the Harvard University health plan and comparing the plan choices of new employees with those of senior employees of similar age groups and sex. Empirically, it was shown that lower-than-expected movement occurred between those plans that were significantly different from one another, thus illustrating the status quo bias.

Another term that has been applied to this type of phenomenon is “endowment effect.” Individual choices are affected by their current endowment. In the case of income, it is the income level that is consequential, but if it is health then it will be deteriorations of health status that will be viewed with concern. This concern with preserving one’s current endowment level leads to a willingness-to-accept amount that often exceeds the willingness-to-pay amount.

A somewhat different phenomenon that seems to be particularly pertinent to pharmaceutical cases is that of regret avoidance based on regret theories of Bell and others. In these models, individuals place a premium on avoiding situations in which they may regret a choice that they have made. In particular, choices that may have large negative impacts are especially prone to regret. On the one hand, if an FDA official approves the next thalidomide, there will be substantial motivation for regret about this type II error. On the other hand, if there is a type I error and the official simply fails to approve a drug that could have averted adverse health outcomes, there will be less of a
chance of ex post evidence contradicting the original decision and, therefore, less potential for regret. Thus, in the pharmaceutical case, the way in which the regret notion becomes embodied is through the asymmetry in the timing of relevant information, thus making regret more important for type II errors than for type I errors.

The final set of irrational biases observed pertain to omission effects (Schweitzer\(^{11}\)). In particular, individuals have a distinct preference for decisions that involve inaction, or errors of omission, rather than situations that involve errors of commission. This phenomenon directly parallels the type I–type II error decision context facing the FDA and has been borne out in choice context more generally.

**Consequences of Asymmetry for Valuation**

To examine the role of asymmetry, this article will consider consumers’ responses to individual risks. This study was undertaken in response to the US Environmental Protection Agency’s effort to examine the value of a wide variety of health outcome associated with environmental policies. The health outcomes addressed in past studies by Magat and Viscusi include: skin burns, childhood poisonings from various products, chloramine gasings, chronic bronchitis, auto fatalities, fat lymph cancer, nonfatal lymph cancer, and peripheral neuropathy. The specific health outcomes to be addressed in this study are those associated with household chemical products. Although the discussion here will focus only on the summary designation of these classes of risks, this survey included detailed discussions of the nature of the health outcomes and the implications of these outcomes for the well-being of the respondents. In the case of the health outcomes considered here, the characterization of the health consequences was developed in collaboration with officials from the Duke University Hospital Poison Control Center.

The effect of asymmetric responses to risk on the discrepancy between willingness to pay and willingness to accept is evident particularly in a study of consumer product risks by Viscusi et al\(^{8}\) and Magat and Viscusi.\(^{12}\) In their studies, individuals were given an opportunity to purchase successive reductions in various risks associated with household chemicals. The initial risk was 15/10,000 and they were permitted to purchase reductions in the risk in increments of 5/10,000 through paying higher prices. The consumer’s maximum willingness to pay for these additional risk reductions is indicated in Table 3. Individuals have a positive willingness to pay for greater safety; this amount diminishes with the second increment of risk reduction that is purchased, which is consistent with rational economic behavior. However, for the next increment that leads to the certainty of risk elimination, there is a jump in the willingness to pay for the risk decrease of 5/10,000. This increase reflects the premium that individuals are willing to pay for the certain elimination of the risk.

If the willingness-to-pay and the willingness-to-accept values were symmetric, one would expect the willingness-to-pay amount for a decrease in the risk from 15/10,000 to 10/10,000 to equal the price cut that individuals would demand for a risk increase from 15/10,000 to 20/10,000. In pretest, individuals were asked how much of a price decrease that they would require to be compensated for a risk increase of 5/10,000. However, in the pretesting of this survey question the universal response was that they would not buy such a risky product at any price. In an effort to accommodate these extreme reactions, the survey instead addressed situations in which the risk increase was 1/10,000. Even with this very moderate risk change, there were extreme reactions on the part of the respondents. As is indicated by the results in Table 3, approximately 70%
of the respondents refused to buy the product at any price. These respondents indicated that they would not accept the product even for free and even if they were also compensated for using the product.

For the segment of the consumers who were willing to accept a price cut for this risky product, the amount of the compensation required for the risk increase was comparable with what they were willing to pay for a risk decrease that was five times as great. In short, there was considerable asymmetry in the character of responses that would lead to quite different implicit values of the health outcome. In the case of the willingness-to-pay amounts for one set of risks in Table 3, such as those associated with a risk decrease of 5/10,000, the implicit value of the health outcome is $420. However, for the willingness-to-accept amount, for the individuals who report finite values, the implicit valuation of the health outcome is $28,600. Thus, there is a more than sixty-fold increase in the magnitude of the risk-dollar trade-off when it is viewed in terms of the amount people are willing to spend (or willing to accept) per unit risk. This amount exceeds what would be predicted based on any standard rational economic model.

The study of auto safety risks by McDaniel’s also documented this phenomenon. Similar types of discrepancies are reported in other contexts dealing with health risks. The studies by Bowker and MacDonald, Knetsch, and Shogren et al all deal with valuation asymmetries in the context of health and safety. In Bowker and MacDonald, respondents who felt that a local pollutant posed a health hazard demonstrated a greater asymmetry of preferences than those that did not. Knetsch found that 61% of surveyed individuals refused to accept $700 for an increased risk of accidental injury, whereas only 27% were willing to pay $700 for a similar risk decrease. Shogren et al showed that subjects exposed to iterative trials come to treat valuations symmetrically for substitutable mar-

---

**TABLE 3. Valuation of Incremental Risk Reductions for Household Chemicals: Incremental Willingness to Pay (Dollars/Bottle) for Risk Decreases of 5/10,000 from Different Starting Risks**

<table>
<thead>
<tr>
<th>Starting Risk (injuries/10,000 bottles)</th>
<th>Insecticide</th>
<th>Toilet Bowl Cleaner</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Inhalation-Skin Poisoning</td>
<td>Inhalation-Child Poisoning</td>
</tr>
<tr>
<td>15</td>
<td>1.04</td>
<td>1.84</td>
</tr>
<tr>
<td>10</td>
<td>0.34</td>
<td>0.54</td>
</tr>
<tr>
<td>5</td>
<td>2.41</td>
<td>5.71</td>
</tr>
</tbody>
</table>

*aSource: Viscusi, Magat, and Huber (1987), p. 475.

---

1 In this study, two experiments regarding auto safety are conducted to test the theory that valuation of safety is invariant to changes in reference points. The first experiment elicits willingness-to-pay and willingness-to-accept measures for increments and decrements in auto safety. In the second, willingness to pay for increased safety is contrasted with willingness to accept decreased safety and features that are industry standards are compared with those that are not.

4 A number of other studies have dealt with valuation discrepancies in other contexts. In general, these studies can be classified as either laboratory experiments using market goods or contingent valuation surveys of environmental amenities. Important experiments using market goods include Coursey et al, Kahnemann et al, and Knetsch. Environmental surveys that investigate the valuation asymmetry include Bishop and Heberlein and Van Kooten and Schmitz.

---

These results are based on the inhalation–skin poisoning injury pair. For an explanation of how to derive implicit values of statistical injuries, or deaths, from values placed on incremental changes in the risk of injury or death, see Appendix A.
ket goods but not for health risks (food poisoning).

Information regarding industry standards also proved to be important. When told that the safety device in question is an industry standard, the number of persons willing to pay $700 leapt to 60%. Similarly, after being told that the safety feature in question was not standard among other models, the number valuing safety at more than $700 (in a willingness-to-accept framework) fell to 44%. This higher valuation of safety associated with prevailing industry standards suggests that consumers place a premium on safety levels associated with established standards. This preference is consistent with the valuation patterns reflected in the status quo bias and related phenomena.

**Implications of Asymmetry for Survey Design**

When dealing with valuing health outcomes associated with a pharmaceutical product that will diminish risk, the appropriate matter of inquiry is the patient's willingness to pay for the risk reduction. If, however, the outcome being valued is an increase in risk, such as an adverse reaction to a drug, what is at stake is the patient's willingness to accept this risk. Unfortunately, the willingness-to-accept values may be contaminated by the excessive responses to risk noted above. If the objective is to attach a specific valuation figure to the health outcome, then one presumably would want to purge the willingness-to-accept amount of these sources of extreme reactions.

Although this is the more usual economic perspective, it should be emphasized that it is not always without controversy in particular instances. Suppose, for example, that individuals are particularly reluctant to experience increases in risk, compared with their willingness to spend to achieve decreases in risk. The extent of the asymmetry may appear to be unduly large, possibly because they do not want to experience regret over errors of commission. However, it is not obvious that economists should override these concerns. If this regret does, in fact, represent a legitimate loss in welfare, but simply not one that is captured within a highly stylized economic model, then perhaps it should not be dismissed. As a result, a more appropriate course of action in which there is a stark asymmetry between the valuation of increases and decreases in risk is that one should attempt to explore the cause of this asymmetry and determine whether this asymmetry should be recognized as a legitimate concern or is a result of a deficiency in the valuation mechanism that should be eliminated from consideration.

One way to adjust for the willingness-to-accept bias is to focus on the willingness-to-pay amount for a risk reduction and to use this figure as a lower bound. Although the willingness-to-accept amount generally will exceed the willingness-to-pay amount, for very small changes in risk these amounts should be quite similar. As a result, the valuation of the health outcome that one obtains using a small decrease in risk will be quite similar to an appropriate willingness-to-accept amount.

One way of determining the willingness-to-accept amount is to run a survey based on willingness to pay and then use these survey results to estimate individual utility functions. In particular, this is the approach used by Evans and Viscusi with respect to aforementioned consumer product risks shown in Table 3. If the survey is used to elicit two situations for which the respondent is indifferent, such as a wage job risk combination.

---

**The first experiment demonstrated loss aversion with a willingness to accept/willingness to pay ratio of 3.6. This number should be seen as a lower bound, however, because many subjects refused to accept any amount as compensation for a lower safety level (and were thus recorded as protest votes). The second experiment shows the importance of framing. In a willingness-to-accept framework, 82% of the subjects valued decrements to their safety at more than $700. In contrast, a willingness-to-pay question revealed that only 46% of the subjects valued similar increments in safety at over $700.**

DS42
from one job that is viewed as equivalent to a wage job risk combination for a second job, then it is possible to estimate the character of individual preferences. In the case of job risks, this leads to estimates of individual utility functions for good health and for injuries. From these utility functions, one can then determine how much the implicit value of a statistical injury varies depending on whether it is a risk increase for which there is a willingness-to-accept amount or a risk decrease for which there is a willingness-to-pay amount.

Viscusi and Evans\textsuperscript{21} used a survey of chemical workers to derive utility functions for wage–risk trade-offs. From this data, the implicit value of an injury was derived for increments and decrements of risk. Valuation of an injury was found to increase at an increasing rate for increments in risk and decrease at an increasing rate for decrements in risk. The ratio of implicit injury value at maximum risk to minimum risk was found to be 1.62. This disparity reflects an underlying asymmetry between a workers’ willingness to pay for risk reductions and that person’s compensation demanded for risk increases even within the context of a fully rational economic response.

In much the same way, Evans and Viscusi\textsuperscript{22} estimated the consumer utility functions that govern the valuation of household poisonings. In that case, the injuries were viewed by the respondents as being tantamount to monetary equivalents. That is, the injury did not affect the structure of preferences as would occur, for example for an injury such as brain damage. Once this is the case, then individuals will treat the injury as being tantamount to a drop in income.\textsuperscript{11}

If these injuries truly are equivalent to monetary outcomes, the individual’s willingness to pay to avoid an X dollar monetary loss will equal X dollars, and the individual’s willingness to accept to incur an X dollar loss also will be X dollars. Money and monetary equivalents are the only currency of concern so that a discrepancy between the willingness-to-pay and willingness-to-accept values can be eliminated in the case of certain shifts in health status.\textsuperscript{11}

A variety of other survey issues also seem to affect the disparity between willingness to accept and willingness to pay. Survey responses in laboratory settings, such as hypothetical classroom experiments, seem to be more subject to bias than those surveys obtained in field context. This may be the result of respondents’ failure to take hypothetical experiments as seriously as those that have a greater appearance of reality.

The currency in which the transactions occur often is consequential. Hypothetical biases for responses can be a problem, particularly for commodities that are not traded regularly in the market, such as environmental amenities. Surveys that more accurately reflect a market context—such as those patterned after marketing studies, as in the case of the consumer risk study—are more likely to yield meaningful assessments than those that do not.

The character of the risk examined also matters. Substantial literature has documented the difficulties individuals have in thinking about making decisions involving low probability events. Indeed, in large part because of these difficulties, an entire line of research in the fields of psychology and economics has emerged. Many of these difficulties are not random, but are in fact systematic. In particular, individuals tend to overestimate the risks associated with low probability events called to their attention.

This bias has important consequences for survey design. In a predecessor to the con-

\textsuperscript{11}If the respondent views the risk as being as bad as a monetary loss, but not equivalent to it, then income effects may play a minor role.

\textsuperscript{11}For example, for insecticide skin poisonings the implicit value of the injury was $624, whereas the monetary equivalent for the same injury was $619. Similarly, toilet bowl cleaner gassings had an implicit value of $490, whereas the monetary equivalent for the same injury was $486. The difference in these values is inconsequential.
sumer product risk survey discussed above in Tables 3 and 4, consumers instead were faced with the opportunity to purchase risk reductions involving risks on the order of 1/1,000,000 or less. That study yielded quite different implicit valuations of the health outcome involved. In particular, the valuation of the health outcome was implausibly large and was orders of magnitude larger than the value solicited when more meaningful probabilities were used. In particular, in the first study the implicit value of an injury from household chemicals was found to be $6.5 million to $1.78 million for an initial risk of 1/1,000,000. An initial risk of 15/10,000 led to implicit valuations of injury from $700 to $3,500. Clearly, the valuation of the smaller risk is biased upward. Indeed, respondents seem to be very insensitive to the magnitude of the risk. Quite simply, low probability events are very difficult for individuals to process sensibly. The practical result for surveys is that even modest willingness-to-pay or willingness-to-accept amounts for very minuscule risks may imply enormous risk-dollar trade-offs.

**Conclusion**

The classic pharmaceutical risk decision involved the trade-off between errors of commission (type II errors) and errors of omission (type I errors). The FDA has placed greatest emphasis on minimizing the type II errors. However, failure to account for all of the risks associated with pharmaceutical products in a comprehensive manner will lead to policies that may in fact not reduce risks as much as possible. For example, if a product increases the mortality risk by P and decreases the mortality risk by Q, where Q exceeds P, then on balance the product will increase longevity. Overall, from a decision-theoretic point of view we should look at the net risk associated with the product and not treat the component parts differently.

This same type of difficulty, unfortunately, also impedes individual choices. In the case of risk reductions, the matter of concern is individuals’ willingness to pay for a decrease in risk. For risk increases, attention turns to individuals’ willingness to accept compensation for an increase in risk, which in turn can be used to assessed their valuation of a health outcome. Although these amounts may differ—one might expect the willingness-to-accept amount to be slightly larger or approximately the same as the willingness-to-pay amount—in practice matters are quite different. For a variety of reasons, individuals tend to overreact to increases in risk, leading to a substantial divergence be-

**TABLE 4. Responses to Risk Increases of 1/10,000 for Pairs of Product Risks**

<table>
<thead>
<tr>
<th>Injury Pair</th>
<th>Percentage for Whom Product is Too Risky to Purchase</th>
<th>Mean Value ($/bottle) of Positive Responses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insecticide</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inhalation–skin poisoning</td>
<td>77.2</td>
<td>2.86</td>
</tr>
<tr>
<td>Inhalation–child poisoning</td>
<td>68.1</td>
<td>3.19</td>
</tr>
<tr>
<td>Toilet Bowl Cleaner</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Eyeburns–gassing</td>
<td>61.5</td>
<td>5.52</td>
</tr>
<tr>
<td>Gassing–child poisoning</td>
<td>74.3</td>
<td>1.28</td>
</tr>
</tbody>
</table>

*This question asked subjects what price discount they would require on the new product to accept an additional risk of 1/10,000 for both injuries, starting with risks of 15 injuries per 10,000 bottles sold for both injuries. See Viscusi, Magat, and Huber (1987), p. 477.*
between the stated willingness-to-pay and willingness-to-accept amounts.

As a first step to addressing this disparity, the analysts should first ascertain why it has arisen. Is it because people have misestimated the change of the risk and are unduly alarmed by risk increase? Or is it because they will experience much more substantial regret if they take an action that leads to an error of commission. Analysts may attempt to persuade individuals that some of these concerns that should not be included, but it is important to distinguish which of these causative factors do represent true irrationalities that should be dismissed as opposed to deviations from usual economic assumptions that should be recognized.

The recognition that for legitimate cognitive reasons individuals may value risk increases more than risk decreases has potentially important implications for the way the FDA treats type I and type II errors in new product approvals. Acting as an agent for consumers of pharmaceutical products, FDA decisions should reflect differential values for increases and decreases in its own valuation of the relative costs (ie, increases in the risks from side effects) and benefits (ie, improved health status from the therapeutic effects) of new products. Thus, consideration of individual attitudes toward risk provides a rationale for the FDA to weight type II errors somewhat more than type I errors in some cases.

In an effort to overcome the limitations of estimates for the willingness-to-accept amounts, a more immediate solution is simply to use a valuation of a health outcome based on a willingness-to-pay figure. This amount will tend to be somewhat smaller than the willingness-to-accept amount, but will establish a floor for valuation. Other more refined methods, such as obtaining direct estimates of the character of individual preferences—or utility functions—also are possible. Regardless of the approach one takes, it is likely that adequately addressing the disparity between these valuations for the individuals involved will prove to be the same kind of continuing concern for analysts as it has been for government policy makers designing pharmaceutical regulation strategies.

References


DS45


Appendix A.
Calculation of Statistical Values for Injuries and Death

To see how these willingness-to-pay or willingness-to-accept values for risk changes are converted into valuations of a health outcome consider the following example. Suppose that you are willing to pay $5 in return for a drug that will reduce your mortality risk by one in a million. How can this response be used to assess your valuation of the health outcome? If one million consumers such as yourself were faced with such an option, on average there would be one statistical death. In return for preventing this death, your group would be willing to spend $5 million ($5 × 1,000,000 patients). Economists would then refer to this $5,000,000 figure as your statistical value of life. Much the same kind of calculation would be done in the case of risk increases so that, for example, a $6 compensation amount that is required to experience an increase in risk of one in a million would translate into an implicit value of life of $6 million. How then should such numbers be used?

In contexts involving pharmaceutical products, the risks are small. From the standpoint of valuing the health outcomes, the matter of concern is the implicit value of small changes in risk, not values of the certain outcome of death or other consequences associated with the drug. If we were, in fact, valuing certain death or certain loss of one’s health, then we would think about this issue quite differently then if we were dealing with statistical risks to our lives. The appropriate valuation of the health amount outcome is the individual’s willingness to pay for the risk reduction involved. If the actual risk being reduced is two in a million and the implicit value of life is $5 million, then it is worthwhile to purchase the drug provided its cost does not exceed $10. Thus, the implicit value of life figure gives the rate of which individuals will spend money to reduce risks to their lives.a

---

aIn practice, these amounts will differ depending on the magnitude of the risk changes involved. In the case of job injuries, it is shown in Viscusi and Evans21 that the implicit value of the injuries is not particularly sensitive to the amount of the risk change involved, even for fairly large changes in risk.