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BRIEFLY NOTED

The EU's Energy Price Controls

●◆ BY PIERRE LEMIEUX

he Russian state corporation Gasprom has dramatically reduced the supply of natural gas to Europe to punish European states for their support of Ukraine. This affects the price of electricity in Europe, of which a large proportion is produced by gas turbines. Gas is also used directly for heating many European homes.

Even before the cut in Russian supplies, prices of gas and electricity in the world had increased because of high demand after the COVID episode and little supply growth following a period of lower investment. Now, some European national governments have instituted new price ceilings on gas and electricity purchased by households and small and medium businesses.

After meeting on October 20–21, the Council of the European Union formally called for an EU effort to cap the price of gas, including a lower cap on its price in electricity generation, and a possible common cartel agreement to pay lower prices for wholesale gas purchased from producers in foreign countries. The legal verbiage of the Council is indicative of its large and contradictory ambitions. The same document describes one of its goals as

mobilising relevant tools at national and EU level. At the same time, the immediate priority is to protect households and businesses, in particular the most vulnerable in our societies. ... All relevant tools at national and EU level should be mobilised to enhance the resilience of our economies, while preserving Europe's global competitiveness and maintaining the level playing field and the integrity of the Single Market. ... The Council ... is committed to further reinforce our coordination, in order to deliver a determined and agile policy response.

PIERRE LEMIEUX is an economist affiliated with the Department of Management Sciences of the Université du Québec en Outaouais. Political factors will have a decisive influence on whatever legislation the EU ultimately adopts toward these ends. But the current intentions provide a good opportunity to review the economic effects of price caps.

Demand and supply of energy / Recall from economic theory that, on a competitive market, if a price is capped below its equilibrium level where quantity supplied is equal to quantity demanded, the former decreases and the latter increases. A shortage in the technical sense develops. (See "Dispelling Supply Chain Myths," Summer 2022.)

Some people think that energy products are somehow not vulnerable to this because they are "essential"-that, because energy is so important, people can little moderate their consumption of it. But what is "essential" is a matter of degree. A 2018 working paper by University of California at Berkeley economists Maximilian Auffhammer and Edward Rubin estimates the elasticity of demand (the proportional change in quantity demanded relative to a proportional change in price) for natural gas in California at about -0.2, meaning that a 10% increase in the price will reduce quantity demanded by 2% over a year. The demand for gas is relatively "inelastic," but a price increase still brings a lower quantity demanded. More recently, in the wake of higher industrial power prices, the Financial Times reported a 30% reduction in the industrial use of energy in the Netherlands for the first five months of 2022. A reduction of the same order by German households was also observed.

To prevent shortages and blackouts, European states imposing price caps for some buyers have paired them with subsidies to producers of gas and gas-produced electricity. Part of these subsidies is financed with taxes on so-called "windfall" profits of energy producers, including non-gas producers such as solar and wind, which have also benefited from higher energy prices as prices of substitutes move together. Of course, energy producers that get their "excess" profits taxed away because their past investments are bringing higher returns than expected will take into consideration this asymmetry between upside and downside risk when planning their future investments.

Crucial function of prices / At the source of the detrimental effects of price controls is the fact that they disrupt the signaling and coordination function of prices. A price is a signaling device that informs buyers and sellers of the relative scarcity of the good (or service) in question.

In his famed 1945 American Economic Review article "The Use of Knowledge in Society," economist Friedrich Hayek gave a useful illustration of the role of prices. Suppose, he explained (I am adapting his example), that the supply of bauxite (the ore used to make aluminum) decreases because of some events in mining somewhere in the world, or alternatively that its demand increases because, say, the consumption of beer in aluminum cans increases in some country. Aluminum thus has become relatively scarcer, and this fact must be communicated to the producers and consumers of aluminum everywhere, so that the latter be incited to consume less and the former to produce more. An increase in the price of aluminum will transmit this signal and matching incentives to reduce consumption and increase production.

Why socialism doesn't work/ True price signals are so important for prosperity that, in the first half of the 20th century, some socialist-minded economists developed a theory of "market socialism." These economists were trying to respond to Ludwig von Mises, who had argued that efficient calculations of costs and benefits are impossible under socialism because there is no market-determined price for capital (the means of production, belonging to the government by hypothesis) and for labor services. Market socialists argued that the "Central Planning Board" could determine prices by a process of trial and error, until quantity supplied and quantity demanded is in equilibrium on every market.

Hayek countered that this will not work because the members of the Central Plan-

the market for an input (in this case, natural gas) into two different markets, one for electricity and the other one for other goods, will divert too much of the input to the government-favored good (electricity) compared to what this good really costs and to the lower value consumers assign to it (compared to other goods). Here again, in its circumvoluted formulation, the EU's goal is to have other people's cake and eat it too: it wants "a temporary EU framework to cap the price of gas in electricity generation, including a cost



ning Board have no way to collect all the information dispersed across the minds of all individuals in all their personal and business circumstances. Nor can the planners recreate the incentives automatically transmitted by prices. Hence, the shortages or surpluses (unsold goods) typical of a socialist economy.

A binding price cap (one that is below the free-market price) blurs the signaling across the economy of the real cost or scarcity of the affected good and of the real price that consumers are willing to pay. It increases quantity demanded and reduces quantity supplied. It prevents individuals from bidding up the prices of goods and services in short supply. It replaces voluntary market cooperation by coerced coordination through laws and regulations.

Note that breaking by legislative fiat

and benefit analysis ... while preventing increasing gas consumption, addressing the financing and distributional impacts and its impact on flows beyond the EU's borders."

Price caps and redistribution / Note also that if the state's goal is to redistribute income, it should do so directly and openly, not confusingly through price controls. If a government thinks that what poor households are willing to pay for gas does not represent its true value for them, a cash subsidy would be the efficient solution. The subsidized poor may not actually want all the gas the government decrees they "need" because they may need something else even more. A price cap, even modulated, is a subsidy that prevents the assisted consumer from

making this choice because he is incentivized to buy all the electricity he wants, at least up to an arbitrary amount.

The International Monetary Fund has correctly argued that European governments should provide targeted support to the poor instead of interfering with market prices. Even the EU's "Regulation on the internal market for electricity" mentions the goal of "enabling market signals to be delivered for increased efficiency." It's the same phenomenon we see in America: the rulers, or some of them, pay lip service to markets as they adopt opposite policies.

Optimism? / In October, some evidence appeared that price signals still work despite European governments' inefficient interventions and their plans for more of the same. Prices of natural gas in Europe had started to decline and were close to, and sometimes below, their levels before the invasion of Ukraine. This is because, on the one hand, the quantity of gas demanded decreased and, on the other hand, other forms of energy (coal, renewables, imported LNG) had partly substituted for gas in the production of electricity. Perhaps we can hope that European price caps will turn out to be non-binding.

In a *Financial Times* column in late October, economics editor Chris Giles predicted that price signals would continue to feed the reduction of energy prices. "The price signal has done its job," he wrote. "Advanced capitalist economies are remarkably successful in this regard."

But there is a minimum condition for this optimism: that European governments don't muddle price signals even more.

READINGS

 "Natural Gas Price Elasticities and Optimal Cost Recovery under Consumer Heterogeneity: Evidence from 300 Million Natural Gas Bills," by Maximilian Auffhammer and Edward Rubin. National Bureau of Economic Research working paper no. 24295, February 2018.

 "Economic Calculation in the Socialist Commonwealth" (1920), by Ludwig von Mises. In *Collectivist Economic Planning*, edited by F.A. Hayek; Routledge & Kegan Paul, 1935, pp. 87–130.

"The Use of Knowledge in Society," by Friedrich A.
Hayek. American Economic Review 35(5): 519–530.

Biopharming Has a Tough Row to Hoe

🔸 BY HENRY I. MILLER AND KATHLEEN L. HEFFERON

btaining medicines from plants is not new. Aspirin was first isolated from the bark of the willow tree in the 18th century, and many other common pharmaceuticals have been purified from the world's flora. These medicines include morphine, codeine, digitalis, the laxative Metamucil, and the anti-cancer drugs paclitaxel

and vinblastine. A notable plant-derived product that has emerged from traditional Chinese medicine is artemisinin, an important treatment for malaria.

Spurred by the COVID-19 pandemic, many laboratories are reorienting their research to not only look at promising compounds that occur naturally in plants, but also to manipulate plants to produce high-value pharmaceuticals, a practice called "biopharming." Academics and biotech companies are using molecular genetic engineering techniques to reprogram plants—including corn, potatoes, rice, and bananas, among others—to produce significant concentrations of pharmaceuticals, including vaccines. Unfortunately, this promising research is being hindered by overregulation.

Why biopharming? / Biopharming's great promise lies in using genetic engineering techniques to make old plants do radically new things, often more cheaply than is possible with non-plant platforms. The technology is similar to that used to insert genes into non-plant organisms, as has been done for decades. For instance, the gene that expresses the human insulin gene was inserted into the bacterium *E. coli*, and the genetically modified bacteria have been the source of that critical drug since 1982. Similarly, genetically engineered baker's yeast that contains the gene for a surface protein of the hepatitis B virus has been the source of hepatitis B vaccine since 1986.

There is great potential for cost-cutting in the biopharming process. The energy for product synthesis comes from the sun, and the primary raw materials are water and carbon dioxide. In addition, biopharming offers tremendous flexibility and economy when adjustments in production are necessary. Doubling the acreage of a crop requires far less capital than doubling the capacity of a bricksand-mortar factory, making biopharmed drugs potentially much less expensive to produce than those made in conventional ways. The quality of the final drug can meet the same standards as current fermentation technology using microorganisms, and grain from a biopharmed crop can be stored safely for long periods with no loss of bioactivity.

An example of the basic approach and its advantages is illustrated by the development of a candidate COVID-19 vaccine by Medicago, a Canadian company. Medicago developed a virus-like particle (VLP) of the SARS-CoV-2 virus only 20 days after obtaining the virus's genetic sequence. Instead of using egg- or animal cell-culture-based methods to produce a vaccine, this technology inserts a genetic sequence that encodes the spike protein of the COVID virus into Agrobacterium, a common soil bacterium that is taken up by plants. The resulting genetically modified plants produce a VLP that acts as a vaccine. The VLPs are similar in size and shape to actual coronavirus but lack viral or plant

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nucleic acid and are thus noninfectious.

Previously, Medicago had made VLPs that contain the influenza virus hemagglutinin protein and demonstrated their safety and efficacy in animal models as well as in human clinical trials. The cost of producing a plant-made vaccine based on VLPs is small compared to its conventional counterpart. Medicago estimates that biological proteins such as vaccines and monoclonal antibodies could be obtained from genetically engineered tobacco plants at 0.1% of the cost of current methods. Moreover, these plant-derived pharmaceuticals remain stable at room temperature for long time periods.

A similar approach is being taken by Kentucky BioProcessing (KBP) to create a COVID vaccine. Scientists at the company copied a portion of the SARS-CoV-2 virus and inserted it into the Nicotiana benthamiana plant (a close relative of tobacco) for rapid reproduction. These plants are then harvested and this inactive virus "fragment" is extracted and chemically attached to their proprietary microscopic nanoparticle. That particle is the vector, or carrier, to form the vaccine antigen complex that, when injected, stimulates an immune response. This KBP vaccine (and a similar one to prevent influenza) is currently in clinical trials. An advantage of KBP's approach is that the plant used for production is not used for food, avoiding concerns about possible contamination of food products.

Regulating biopharming / Although biopharming has been under development in academic labs for over 20 years, the path to commercialization has been slow and inconsistent, in large part because of imposing regulatory hurdles. For example, more than a decade ago, a biotech company called Ventria Bioscience solicited the Food and Drug Administration to grant "generally recognized as safe" (GRAS) status to two human proteins, lysozyme and lactoferrin, synthesized in genetically engineered rice. These proteins were intended for use in oral rehydration solutions to treat diarrheal diseases. Research in Peru had shown an oral-rehydration solution with the proteins extracted from Ventria's rice substantially lessens the duration of diarrhea and reduces the rate of recurrence-a near-miraculous advance for people in the developing world. However, Ventria never received any response from the FDA and the product was never marketed.

Without clear, predictable, and reasonable regulatory frameworks, it isn't surprising that pharmaceutical companies, most of which have little experience in working with plants, are reluctant to make

large upfront investments in this technology. Despite these hurdles, commercial biopharming has expanded, and largescale manufacturing facilities have been constructed in the United States, United Kingdom, and elsewhere. Companies such as Medicago, iBio and KBP can currently process thousands of kilograms of plant biomass grown in greenhouses into highly purified pharmaceutical proteins. None of these companies yet has an approved vaccine, but others, such as the UK's Leaf Expression Systems, have begun to sell a small number of biopharmed diagnostic products and laboratory reagents, none of which are currently for human use.

It can be challenging to confine entire plant-based protein expression systems within a clean room or greenhouse environment to conform with Current Good Manufacturing Practices (CGMPs). Nevertheless, the use of contained systems for plant cultures has helped to lessen various regulatory and safety concerns that might constrain production in plants cultivated in open fields.

No plants for biopharming have been approved for cultivation in commercial field production. Some work is taking place in approved, confined research field trials, which require isolation, toxicity data, and oversight by inspectors to witness disposal of residual plant material. Biopharming has, up to now, been restricted to laboratories and greenhouses to prevent introduction into the outdoors environment. These restrictions are a response to concerns such as the possible movement of pollen and the unintentional introduction of plant material containing bioactive substances into food supply chains and accidental consumption by people, livestock, or wildlife.

In 2003, the U.S. Department of Agriculture announced onerous new rules for testing crops engineered to produce pharmaceuticals. The ostensible objective of the regulation is to avoid contaminating food supplies with drugs, especially when edible crops are used to produce them. But concerns of the food industry and regulators that biopharmed plants could

contaminate food products are overblown, and in any case such risk can be mitigated in several ways.

Even if biopharmed crops were to contaminate food crops, how likely is it that consumers would find harmful amounts of prescription drugs in their corn flakes, pasta, or tofu? A combination of factors including natural selection, farmers pursuing their own commercial self-interest, liability concerns, and the vast size of the U.S. food supply—all militate against such a possibility.

Gene flow is a ubiquitous biological fact of life. All crop plants have wild relatives somewhere, and some gene flow commonly occurs if the two populations are grown sufficiently close together. Thus, although genes could be transferred from a crop that has been modified to synthesize a pharmaceutical, the recipient plant is likely to proliferate only if the gene that has moved confers a selective advantage. Such occurrences should be uncommon with biopharming because, most often, the added drug-producing gene should not confer on the recipient any selective advantage and would be more likely to put the plant at a selective disadvantage. Thus, if such a gene were to be transferred into a food crop, it might persist at a low level in the affected crop population for many generations, but we would expect its ability to proliferate and cause significant contamination of the food crop to be limited.

Gene transfer is an age-old consideration for farmers. Farmers in North America and elsewhere, who grow many hundreds of crops-virtually all of which (save only wild berries and wild mushrooms) have been genetically improved in some way-have meticulously developed strategies for preventing pollen cross-contamination in the field when and if it is necessary for commercial reasons. For example, plant breeders' guidelines have traditionally called for keeping distinct varieties of corn-a wind-pollinated crop-at least 660 feet apart. At this distance, the two corn varieties will not hybridize to any great extent, even if small amounts of pollen

might still drift between the fields. Even without government oversight, biopharmers themselves strive to keep their specialty corn sufficiently far from ordinary cornfields, lest their highly valuable drug-producing crops suffer contamination from the food crops.

Finally, as in the KBP COVID vaccine example above, biopharming can be performed in non-food crops such as tobacco and its relatives.

Conclusions / Many biopharmed vaccines and other biologics have been shown to be cheap, safe, and efficacious, and do not require refrigeration or sophisticated medical equipment to distribute them. But these drugs have not yet entered the marketplace in part because of regulatory constraints.

When new restrictions on biopharmed crops were announced in 2003, then-agriculture secretary Ann Veneman told reporters, "It's very important that we regulate in a way that allows this technology to proceed, so we can reap the benefits of it." Instead, the department is regulating in a way that will ensure that the field is stigmatized, that biopharming's research costs are hugely inflated, that only very high-value-added products will be candidates for development, and that consumers ultimately will see few biopharmed drugs in the pharmacy. Moreover, in these circumstances there is little chance that pharmaceutical companies will develop many products designed for less developed countries where heat-stable, biopharmed drugs and vaccines could revolutionize health care.

Regulating the Regulator of Plant Growth Regulators

🔸 BY JOHN J. COHRSSEN

s the world confronts population challenges, limited resources, environmental pressures, climate change, and market competition, advances in agriculture will be essential. They will likely include increased plant productivity as well as more nutritious foods and other new products. However, some of the

very valuable improvements now possible using innovative and cost-beneficial molecular technology such as gene-editing are being stifled by burdensome and costly regulation from the Environmental Protection Agency.

Federal regulation / An example is the EPA regulation of a "plant regulator," which is any agricultural input applied to plants to alter how quickly or large they grow, their maturity, and other desirable characteristics. The Nematocide, Plant Regulator, Defoliant, and Desiccant Amendment of 1959 added these substances to the categories of pesticides regulated under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The law was intended to ensure that chemicals are not "adulterated." It sets tolerances for their use when applied to the exterior of plants, and it includes requirements on the labeling of the contents and directions.

Industry sought the 1959 amendment because no federal law regulated chemicals used as a plant regulator, and states were enacting a patchwork of requirements. Subsequent FIFRA amendments have added the evaluation of plant regulators for possible health and environmental hazards.

Modern genetic engineering technology has made possible the incorporation

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of precise gene-edited plant growth regulators (PGRs) into a plant, an enhancement not directly comparable in its hazard potential to a chemical substance applied externally to a plant. Rather, gene-modulated growth regulation is analogous to the kinds of genetic modification achieved by the slower, less precise, and less predictable processes of conventional plant breeding. Examples include the semi-dwarf, high-

EPA review of gene-edited plant growth regulators has imposed stifling compliance costs on an important segment of U.S. agricultural innovation.

yield, disease-resistant wheat varieties developed by Nobelist Norman Borlaug, the father of the "Green Revolution."

In 1986 the U.S. Coordinated Framework for the Regulation of Biotechnology established what was intended to be a uniform national oversight policy for this research and the products developed through genetic engineering under existing federal law. The Framework addressed the management of the hypothetical unreasonable risks mainly from the combination of genetic material from dissimilar source organisms. The EPA's focus at the time was on genetically modified microorganisms used as pesticides, to produce chemicals, and for other purposes.

Modifying plants / Eight years later, the EPA announced broad new FIFRA policies to regulate genetically engineered whole plants with augmented pest resistance and to expand the definition of a plant regulator to include changes conferred by the genetic modification of a plant.

Arguing for its expanded interpretation of the statutory definition of a "plant regulator," the EPA declared that Congress in 1959 had addressed substances *applied to* plants but failed to clarify how the definition applied to substances *produced within* plants themselves. The EPA speculated that if Congress had known about technologies to modify PGRs via genetic modification, the practice would have been included in the FIFRA definition of a "plant regulator." According to the EPA:

Congress did not provide direct guidance on the implications of the definition of plant regulator for substances produced in plants. EPA, therefore,

> believes that it has the discretion to develop a reasonable approach to defining what constitutes a plant regulator for substances produced in plants.

EPA looked at previous Congressional action

relating to "plant regulators," plant science, the traditional roles of EPA and [the Food and Drug Administration] in this area, and the extent to which risk concerns would go unaddressed if EPA did not include certain plant substances in the definition of "plant regulator."

Thus, the EPA made a broad new rule that a substance produced in a plant as a result of a genetic change in the plant's physiology is a plant regulator when:

It is intended to accelerate or retard the rate of growth or rate of maturation, or alter the behavior of the plants and meets one of the following criteria: (1) Is a plant hormone. (2) Acts to prevent, destroy, repel, or mitigate a pest. (3) Is toxic in concentrations found in the plant (undiluted package).

The EPA further widened the regulatory net, adding:

Plant hormones that are produced in plants as the result of an intentional change in the plants' physiology would be considered plant regulators. As plant regulators, they would also be considered a plant-pesticide and under EPA's authority.

The EPA FIFRA review and labeling of gene-edited PGRs has imposed stifling

compliance costs on an important segment of U.S. agricultural innovation because of the agency's inferred congressional authority to meet a questionable regulatory need. (It should be noted the FDA has regulatory authority over foods derived from plants.)

Biostimulants / The EPA's "plant regulator" definition has caused alarm in the relatively new plant biostimulant industry because some of its products would be subject to FIFRA's high compliance costs. The term "plant biostimulant" was initially adopted to describe substances used in minute quantities that promote plant growth without being nutrients, soil improvers, or pesticides. "Plant biostimulants are not intended to mitigate or kill pests and are not intended to alter the natural growth behavior of a plant in a manner which it would not normally behave under optimal growing conditions," according to the Biostimulants Council, an industry trade group. Biostimulants are biochemical, microbial, or chemical substances that influence the intrinsic properties that modulate the growth of plants, in contrast to fertilizers that simply add nutrients. According to the EPA, "They enhance agricultural processes in the plant and in soil using substances and microbes already in the environment and can promote greater water and nutrient use efficiency." The global biostimulant market was estimated to be around \$2.3 billion in 2020 and is expected to reach \$3.9 billion by 2025. The United States has a significant share of that market.

The EPA's 2020 draft guidance for plant biostimulants focuses on whether they fit the FIFRA definition of a plant regulator, i.e., whether a biostimulant "physiologically influences the growth and development of plants in such a way as to be considered a plant regulator under FIFRA.... A key consideration is what claims are being made for products, which is the focus of this guidance." Depending on the claim for a particular biostimulant, the EPA would determine whether the product has pesticidal properties.

The Washington State Department of

Agriculture explains a definitional nicety:

Most biostimulants seem to focus on secondary functions and claims, for example, that the hormones will increase root growth, which will improve drought resistance. If the claim is drought resistance, producers tend to think it should not be regulated as a pesticide.

The EPA draft guidance notes that certain products are exempt because they are excluded from the legal definition of a plant regulator such as plant nutrients, plant inoculants, soil amendments, and vitamin hormone products. The draft guidance does not identify risks associated with biostimulants.

It should be noted that biostimulants that the EPA does not regulate as pesticides may be regulated as a fertilizer by individual states. The European Union regulates biostimulants as fertilizers.

Turf-building / The EPA has expanded its FIFRA reach by simply broadening the definition of a plant regulator. The agency concluded that even though Congress did not regulate PGRs internal to a plant in 1959, Congress would want the EPA to do so today, even though internal PGRs do not present the chemical risks that prompted the 1959 law. The agency concluded that Congress gave it authority to expand its regulatory scope because "without it, regulatory concerns would go unaddressed." Considering biostimulants as plant regulators raises similar concern about whether the EPA's regulation reflects congressional intent or agency turf-building.

Because some firms fear retribution, industry is not well-positioned to vigorously oppose expansive agency regulation. Other firms may seek competitive advantage from greater regulation. Congress should clarify its intended scope of FIFRA regulation rather than allow a regulatory agency unbounded discretion to presume authority for concerns not specifically recognized by Congress.

To eliminate the threat of suffocating EPA regulation, Reps. Jimmy Panetta (D– CA) and Jim Baird (R–IN) introduced the Plant Biostimulant Act of 2022. It would exclude biostimulants from the definition of "plant regulator" and, accordingly, obviate the necessity for FIFRA compliance. Similar legislation may be introduced in the next Congress.

The two congressmen are similarly concerned about government-imposed obstacles to gene-editing. They recently took remedial legislative action via an amendment to the House-passed "minibus" appropriations bill. The amendment directs the FDA to speed up regulatory modernization and consistency for products of plant gene editing. It directs the Department of Agriculture to modernize the regulatory pathway for genetically engineered microbes, encourage transgenic plant research, and focus on the use of biotechnology to find solutions to agricultural challenges. Importantly, it also requires the USDA and FDA to collaborate on developing needed viable animal biotechnology regulations.

A legislative fix to exclude gene-edited PGRs from the EPA's definition of "plant regulator" that follows the Panetta-Baird proposal to exclude biostimulants from the "plant regulator" definition would remove a troublesome barrier to innovation in plant agriculture. It is encouraging that lawmakers are moving to reinvigorate the role of Congress to rein in regulatory agencies and claw back costly and excessive regulation.

What Are 750,000 Senior COVID Deaths Worth?

🐟 BY THOMAS J. KNIESNER, RYAN S. SULLIVAN, AND W. KIP VISCUSI

he United States has officially surpassed 1 million deaths from COVID-19, a shocking number that was unimaginable two years ago. Those aged 65 or older account for about 750,000 of those deaths. This age distribution raises the question, should the concentration of the deaths among older people affect how we value those deaths?

Identifying fair and economically correct treatment of seniors is difficult for two reasons. First, the recent pandemic has been much harsher on the elderly compared to previous pandemics; for example, the elderly comprised only 1% of deaths in the 1918 flu pandemic. Second, because seniors have shorter life expectancy, it has been suggested that we apply a different economic weight to their loss of life as compared to younger people.

VSL / Focusing on the amount of remaining life offers the allure of quantitative precision but does not address the right economic issue. What matters is how much those affected and society in general are willing to pay to reduce the risks. Should we be willing to pay more, less, or the same to extend the life of an elderly person compared to a younger person? How do economists and government agencies put a dollar value on something as precious as risks to a human life?

The answer lies, in part, in the public policy literature that examines the Value of a Statistical Life (VSL), by which economists estimate how much money people are willing to pay (or be paid) to accept or evade small changes in the risk of death. Analysts use VSL estimates to infer an implicit value of life extension. In particular, workplace studies have examined how much more workers have to be paid

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to take jobs with higher fatality risk (e.g., test pilots versus airline pilots or underground mining versus above-ground mining). Economists have also studied how much individuals are willing to pay for safety improvements such as airbags or bicycle helmets, which reduce fatality rates or injuries.

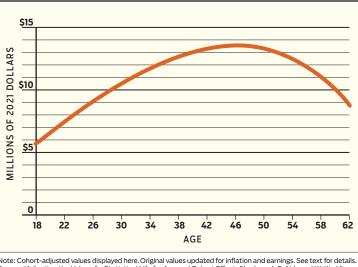
Elderly COVID deaths/ In the United States, there is considerable evidence across numerous product and labor market

FIGURE 1

settings that, on average, people are willing to pay about \$110 for every 1 per 100,000 reduction in fatality risk involved in working or using a product or service. So, as a group, 100,000 people are willing to pay \$11 million for a safer job, product, or life-saving service that would prevent one death from injury or disease. Because the specific life saved would not be known beforehand, this is called a "statistical life," which then yields the VSL. The \$11 million number is similar to the values that the federal Environmental Protection Agency, Department of Transportation, and Department of Health and Human Services apply to the benefits of a life saved.

With rare exceptions, government agencies use the same VSL to value mortality risks of populations irrespective of age, gender, income, the type of death, or other characteristics. A notable case where government agencies made an age adjustment was in the EPA's 2003 analysis of the Clear Skies Initiative, a proposal to regulate power plant air emissions, in which

Value of a Statistical Life by Age



Note: Cohort-adjusted values displayed here. Original values updated for inflation and earnings. See text for details. Source: "Adjusting the Value of a Statistical Life for Age and Cohort Effects," by Joseph E. Aldy and W. Kip Viscusi. *Review of Economics and Statistics* 90(3): 573–581 (2008).

the agency applied a 37% discount to the VSL applied to mortality risks for those aged 65 and over. After a public outcry and complaints from senior citizen organizations such as the AARP that seniors' lives were wrongly being devalued, the EPA abandoned the practice of adopting any senior discount.

Yet, people often behave *as if* there are differences, given who is dying and the type of death. Although the average VSL may be about \$11 million, aggregated data of workers' revealed VSL typically form a hump shape over the life cycle. People's willingness to pay to reduce their risk of death increases as they mature and then declines as they approach old age. See Figure 1.

The greater affluence of older Americans and their lower willingness to accept risks affect their estimated VSL. For example, the estimated VSL in the United States for people aged 55–62 is not materially different than for those aged 18–25. The public outcry over the senior discount used in the Clear Skies Initiative regulatory impact analysis may reflect a societal reluctance to devalue the lives of older people even if their private values are not as great as they were in their 40s.

Determining whether the VSL should be the same for older people or if there

should be age variations in the VSL can have practical implications in the allocation of medical resources. For instance, while ventilators currently are not as scarce as when the pandemic emerged, it is likely that society will have to confront comparable allocation decisions in future health crises. There are also interim near-term decisions that will be affected, such as assessing whether it is worthwhile to have a reserve of ventilators and other medical facilities to address potential future surges in illness. Whether such anticipatory efforts are

desirable hinges on whether the lives that will be extended are accorded a substantial value. If the beneficiary group is older people and their VSLs are discounted, then there may be little inclination to prepare for future pandemics.

In what is sometimes termed a "fair innings" approach, some ethicists have suggested that young people should be given priority for life-saving measures such as ventilator access. The stated ethical rationale is that older people have already had their "turn at bat." Some analysts have offered support for such an emphasis by tallying the number of life years at risk rather than considering the willingness-to-pay amounts. This life expectancy table approach ignores the private benefit values reflected in the VSL, which are grounded in the person's own willingness to pay for the benefit. If peoples' valuations do not plummet with age, then there is no economic rationale for discounting older people's lives.

The estimates depicted in Figure 1 suggest that if we choose to use lower VSL values for the elderly, then we should do the same for the younger population groups in society that have a similar valuation for their (statistical) life. Should we use a lower VSL in cost-benefit analyses for children's vaccination campaigns or when making decisions to protect young soldiers in the military? Using different VSL values across different age groups creates difficult theoretical and moral dilemmas for policymakers, which is a main reason why policymakers have been reluctant to use such age-based adjustments.

Dread / If we choose to adjust the VSL by age, then we should consider adjusting it for other factors as well. For instance, one of the biggest potential adjustments for both the mortality and morbidity effects of a disease such as COVID is *dread*. Particularly dreadful diseases have been found to dramatically increase the VSL, as people report that they are willing to pay more to reduce their risk of death from dreadful diseases in comparison to more "normal" fatalities such as car accidents.

For example, researchers have found

that cancer deaths (which are often skewed toward the elderly) have a VSL premium roughly 21% higher than normal deaths, indicating that people would be willing to pay more to avoid that type of death in comparison to similar fatality risks in society. Other VSL premiums have been found in severe acute respiratory syndrome (SARS), terrorism, and deaths related to influenza. One study put the VSL premium for SARS as high as 435% in comparison to so-called normal deaths.

Should we be making such VSL adjustments across different age groups and different disease types? Making this determination requires finding precise willingness-to-pay estimates corresponding to the VSL. A new disease such as COVID does not have a long list of studies that coalesce around a specific VSL value. It may take years to get to that point. Until the literature becomes more advanced, it makes sense to stick with the default value of the population-average VSL.

Cost-effective policies / If we do conclude that there is no reason to undervalue the lives of the elderly when making policy, what would be part of an economically fair policy for the next pandemic, which may again disproportionately affect the elderly?

Of course, reducing the bureaucratic barriers that slowed the development and administration of a vaccine and widespread testing of the elderly would be obvious components of cost-effective policy. Regulations on outdoor activities do not appear to be part of economically sound policy. Regulations on outdoor dining, for example, save relatively few lives. In addition, recent evidence indicates that socially isolating the elderly to decelerate the spread of COVID has important negative consequences for their mental health.

Another policy implication could lie in the quickly expanding interest in what are called the social determinants of health. Although then–New York governor Andrew Cuomo said that nobody's mother was expendable, his decision to move older patients with COVID into nursing homes appears to have accelerated its spread among the senior population, exacerbated by nursing homes with staffers working at multiple locations.

Aging in place / In a recent national survey, about two-thirds of Americans said they hope to "age in place"—that is, spend their senior years in their homes instead of some seniors facility. But only about one-third of the respondents believe they actually will do this.

Two prominent obstacles cited for this gap between hopes and expectations were concerns over not having enough money saved and poor tech literacy. One longer-run policy potentially emerging from the pandemic might be a greater embrace of the aging-in-place model where more resources (possibly from Medicaid) or different technologies—such as video health provider visits—help keep more people in their homes as they age.

For these and other policies that affect the elderly, the valuation of the benefits should not revert to a simple count of the expected remaining years of life. Such tallies are divorced from the fundamental economic principles for assessing regulatory benefits. The principal driver of mortality benefits is how much affected people value the policies. Application of the VSL remains the correct economic approach.

READINGS

 "Adjusting the Value of a Statistical Life for Age and Cohort Effects," by Joseph E. Aldy and W. Kip Viscusi. *Review of Economics and Statistics* 90(3): 573–581 (2008).

"New Estimates of the Value of a Statistical Life using Air Bag Regulations as a Quasi-Experiment," by Chris Rohlfs, Ryan S. Sullivan, and Thomas J. Kniesner. American Economic Journal: Economic Policy 7(1): 331–359 (2015).

 Pricing Lives: Guideposts for a Safer Society, by W. Kip Viscusi. Princeton University Press, 2018.

• "Pricing the Global Health Risks of the COVID-19 Pandemic," by W. Kip Viscusi. *Journal of Risk and Uncertainty* 61(2): 101–128 (2020).

 "The Forgotten Numbers: A Closer Look at COVID-19 Nonfatal Valuations," by Thomas J. Kniesner and Ryan S. Sullivan. *Journal of Risk and Uncertainty* 61(2): 165–176 (2020).

 "The Value of a Statistical Life: Evidence from Panel Data," by Thomas J. Kniesner, W. Kip Viscusi, Christopher Woock, and James P. Ziliak. *Review of Economics and Statistics* 94(1): 74–87 (2012).

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