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Anti-Science Precautionary Principle Jeopardizes Health, Safety and Risks Innovation

By Wayne Winegarden, May 15, 2020

Medical innovations do not happen overnight. Whether it is gene therapies, new vaccines, or cutting-edge medical equipment, developing innovative medical products is a risky venture. It also takes time, lots of financial resources, and most importantly, human ingenuity. Developing new drugs, for instance, can take between 10 and 15 years.

Now, more than ever, it is imperative that our regulatory framework encourages innovation and protects the intellectual property that makes innovation possible. Otherwise, the medical advancements we desperately need will cease. Unfortunately, it seems that too many countries are doing the exact opposite. If adopted more broadly, these regulatory frameworks could imperil the global supply of critical medical products.

In most sectors, regulations work best when they efficiently manage risks, not when they are designed to simply avoid the worst imagined outcomes. Unfortunately, this regulatory approach, commonly referred to as the *precautionary principle*, has a strong foothold in the European Union based on the old adage: "it is better to be safe than sorry."

The EU applies the precautionary principle by regulating based on the potential for harm rather than proof of harm. And nowhere is this more apparent than in the EU's regulation of chemical substances. While the EU's stated goal is to protect human health and the environment, this approach, ironically, risks the development and use of lifesaving technologies *without* the burden of demonstrating tangible health or environmental benefits.

One timely example is the EU's ongoing and excessive regulation of a group of chemicals called silicones.

Silicone is a chemical commonly found in numerous everyday consumer products, such as cooking utensils and cosmetics. Silicones are also an essential component for many medical technologies based on their unique attributes including hypoallergenic and bacterial-resistance properties.

Medical uses for silicones include common products such as bandages and syringes to more complex applications, such as MRI and CT machines. Pertinent for the global coronavirus pandemic, silicones are an essential component of respiratory tubing and mask seals used in ventilators.

A new potential regulation in the EU – so-called "authorization" – could lead to banning silicones in certain uses and, if adopted widely, could ultimately risk the efficacy of medical devices and supplies. This would include products produced and imported into the EU.

Since these regulations fundamentally disrupt how these devices are made, it would logically follow that strong scientific evidence exists documenting that these compounds are either a significant threat to the environment or public health. Except, this is not the case.

The EU is the only authority in the world that has chosen to restrict silicone use in products, let alone institute a quasi-ban. Canada and Australia have studied these substances using a risk-based approach, including their behavior in and effects on the environment, and have concluded that they do not pose a risk that warrants any of these EU-like restrictions.

So, with decades worth of scientific data, how is it possible that countries like Canada and Australia come to such a vastly different conclusion than the EU? Herein lies the crux of the problem: by using the precautionary principle the EU bases its decisions on perceived harms rather than the available scientific evidence, including exposure data.

While the current scientific evidence does not support the severity of the EU regulations, it is impossible to disprove a counterfactual. Therefore, claims that we should stringently regulate silicones "just in case" are difficult to counter. And, once regulations have been justified based on perceptions, rather than science, it becomes easier to ratchet up these restrictions.

At first glance, the EU's use of the precautionary principle and its effects may seem isolated. But, several countries, including Brazil, Korea, and India, are in the process of determining how best to regulate and manage chemicals. Unfortunately, the EU has been active in trying to encourage some of these countries to adopt its precautionary approach.

If left unchecked, the EU's use of the precautionary principle and its effort to export that approach globally could jeopardize key materials, undermine health innovations in those nations, and could potentially endanger global supply chains.

Nations developing their chemical management processes should instead follow the lead of Australia, Canada, and the US, which have adopted systems that rely on sound scientific evidence, not cherry-picked laboratory studies, which purport worst case scenarios that are disconnected from real-world data.

The EU's silicone regulations may appear to be taking the cautious approach, but once the benefits of chemicals are considered, the large risks of the precautionary principle become clear. These regulations reduce the efficacy of vital healthcare products and jeopardize patients' health outcomes without reducing any scientifically identified risks. More broadly, these trade-offs demonstrate that regulations based on the precautionary principle will often increase risks for society, not decrease them.

Regulations come with costs. In the case of the EU's regulation of silicone, these costs could be the unseen decrease in patients' quality of care. While these costs are more difficult to see, they are no less real. These unseen costs demonstrate that while it is irresponsible for regulators to ignore scientifically identified risks, it is also irresponsible to deny people valuable products based on imagined harms. Nations hoping to encourage health innovation through their regulatory framework should rely on scientific evidence and reject the precautionary principle.

About Wayne Winegarden: I am a Senior Fellow in Business and Economics at the Pacific Research Institute and the Director of PRI's Center for Medical Economics and Innovation. My research explores the connection between macroeconomic policies and economic outcomes, with a focus on the health care and energy industries. I have over 25 years of experience advising Fortune 500 companies, medium and small businesses, and trade associations. I received my Ph.D. in economics from George Mason University.