

Michigan Science

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COMING SOON

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BY THE NUMBERS

Beyond propaganda and rhetoric, numbers tell the real story

THE NATIONAL ASSESSMENT of

Educational Progress revealed that scores of eighth-grade mathematics students in the United States have ticked slightly upward in the past two years. NAEP reports that scores rose from an average 281 score in 2007 to an average 283 score in 2009. Despite the rise in score averages, only 34 percent of students nationwide are attaining or exceeding established proficiency levels.

For more information, visit www.wwj.com/pages/5625507.php.

TWO 2009 POLLS indicated that although a majority of Michigan residents would support an increase in recycling household waste, actual recycling levels have decreased in the state since 1998. According to the survey conducted by Marketing Resource Group, 81 percent of residents believe that a more comprehensive state-wide program to recycle a wider variety of household wastes would benefit the state. Another poll, conducted by Public Sector Consultants, revealed that the state's per-capita recycling rate decreased 28 percent between 1998 and 2008, reflecting a drop from 0.36 tons to 0.26 tons.

For more information, visit www.wwj.com/Report--State-Won-t-Recycle-Despite-Promise-Of-13-/5663911.

AT 17 MILLION tons in 2005, the United States' consumption of potatoes ranks fourth internationally, behind first-place China, which consumed 47.5 million tons in the same year. It is estimated that each person in the United States consumes more than 119 pounds of potatoes each year, and that 309 million tons were produced worldwide in 2007. Originally exclusive to



South America, potato cultivation has spread to every continent except Antarctica over the past 7,000 years, and potatoes have become a major source of sustenance. The Potato Genome Sequencing Consortium, a team of 39 scientists from 14 countries, has completed the first draft of its project, which it began in 2006. The Consortium estimates that the complete genome of 95 percent of potato genes consists of 840 base pairs, nearly one-fourth of the base pairs in the human genome. This data will assist plant biologists in developing drought- and disease-resistant potatoes.

For more information, visit www.potatogenome.net/index.php.

UNIVERSITY OF MICHIGAN researchers set a record in fiscal 2009 with 350 new inventions – breaking the previous record of 329 set in 2007. The university also reported a 20 percent increase in royalties during the same period for technologies developed there. Fiscal 2009 royalties

reached \$15.1 million. Technology transfer revenue earned equity returns of \$3 million, bringing the total revenues to \$18.1 million. Additionally, UM announced eight new faculty startups for fiscal 2009, bringing the total to 83 since 2001. Patent applications by UM researchers rose 14 percent over fiscal 2008 to reach 151, while 72 patents were granted and 78 technology contracts were issued to existing and startup businesses. All told, UM researchers surpassed the \$1 billion research expenditure mark for the first time.

For more information, visit www.michigantoday.umich.edu/2009/11/story.php?id=7572.

AT LEAST NINE of the 35 states that have set goals to obtain more electricity from such renewable energy sources as solar panels and windmills have fallen short, according to an article by Traci Watson in USA Today. According to the article, New Jersey, California, Arizona, New York, Ohio, Maryland, Massachusetts, New Hampshire and Delaware all fell short of established goals. New Jersey, for example, will miss a deadline to generate 1,000 megawatts of electricity from offshore windmills by 2012. California's goal to generate 20 percent of its energy needs from alternative sources by 2010 won't be met until 2013 or 2014; Arizona will not reach its 2009 goal of 0.3 percent electricity derived from solar power until at least 2011; and New Hampshire only met two-thirds of its 2008 renewable energy commitment. Despite this, the U.S. House of Representatives passed a bill last June increasing mandated energy derived from renewable sources from 9 percent to 15 percent by 2020.

For more information, visit www.usatoday.com/money/industries/energy/2009-10-08-altenergy_N.htm.

FIELD TRIPS

Area science museums host special programs of interest for budding scientists and their families



THE GREAT LAKES Naval Memorial and Museum offers visitors the chance to tour two historic vessels and learn about the history and science behind World War II naval warfare. Exhibits offer the chance to learn about the difference between passive and active sonar, how periscopes work and how submarines dive and surface. Berthed near the Pere Marquette Park on Lake Michigan in Muskegon, the GLNMM also offers tours of the USS Silversides, the most decorated surviving submarine from World War II, and the USCGC McLane, a 1927 Coast Guard cutter. Groups can register for a private tour and overnight stay on one of the ships.

Call 231-755-1230 for details. Great Lakes Naval Memorial and Museum, 1346 Bluff, Muskegon, MI 49441. Hours and rates vary by group and season.

For more information, visit www.glnmm.org

THE ALDEN B. DOW Museum of Science and Art in Midland is featuring *Waterworks: Soak Up the Science!* Visitors can make a rainbow, play “water pinball,” pilot a model submarine and learn about water cycles and transformations through the adventures

of “Walter the Water Molecule.” Interactive exhibits show how to harness the power of water and describe the importance of water’s role in everyday life.

Runs from Jan. 28 through May 31, 2010. Alden B. Dow Museum of Science and Art, 1801 W. Saint Andrews Rd., Midland, MI 48640. Museum is open Wednesday, Friday, and Saturday, 10 a.m. to 4 p.m.; Thursday, 10 a.m. to 6 p.m.; Sunday, 1 p.m. to 5 p.m.; closed Mondays and Tuesdays. Adults: \$8, children (4-14): \$5. Call 989-631-8250 or 800-523-7649.

For more information, visit www.mcfta.org



ANN ARBOR HANDS-ON Museum is hosting *Bob the Builder™ — Project: Build It*, the first-ever Bob the Builder traveling museum exhibit. Children can complete fix-it activities, experiment with tools in Bob the Builder’s workshop, discover how to install sink parts

in Bob’s mobile home and learn about water conservation.

Runs through March 14, 2010. Ann Arbor Hands-On Museum, 220 E. Ann St., Ann Arbor, MI 48104. Museum is open Monday-Saturday, 10 a.m. to 5 p.m.; Sunday, noon to 5 p.m.; open Tuesdays at 9 a.m. Adults and children (2 and up): \$9; members: free. Call 734-995-5439.

For more information, visit www.aahom.org.

IMPRESSION 5 IN Lansing is hosting *Your Spitting Image*, a traveling exhibit devoted to oral health. The exhibit not only promotes proper oral hygiene, but it also explores the fascinating world of forensic dentistry and the wonders of saliva. Visitors discover how forensic scientists make identifications by using dental records and DNA samples collected from toothbrushes. Hands-on displays reveal the remarkable properties of saliva. Visitors learn how much saliva humans produce each day, peer through a magnifying glass at saliva molecules and discover how saliva can be used as a diagnostic tool.

Runs through Aug. 2010. Impression 5 Science Center, 200 Museum Dr., Lansing, MI 48933. Center is open Monday-Friday, 10 a.m. to 5 p.m.; Saturday, 10 a.m. to 7 p.m.; Sunday, noon to 5 p.m. Adults and children (5 and up): \$5; children under 5: pay your age; seniors: \$4.50. AAA members receive 10 percent discount. Call 517-485-8116, ext. 32.

For more information, visit www.impression5.org.

Norman Borlaug: An American Hero

CALLED “ARGUABLY THE greatest American in the 20th century,” during his 95 years Norman Borlaug probably saved more lives than any other person.¹ He is one of just six people to win the Nobel Peace Prize, the Congressional Medal of Honor and the Presidential Medal of Freedom. And yet Dr. Borlaug, who died this past September, is scarcely known in his own country.

Born in Iowa in 1914, Borlaug spent most of his life in impoverished nations inventing, improving and teaching the “Green Revolution.” His idea was simple: Make developing countries self-sufficient in food production by teaching farmers how to use modern agricultural techniques that are simple to implement. Borlaug spent most of his time in Mexico, Pakistan and India, and focused on five areas: crop cultivars (seeds), irrigation, fertilizers, pesticides and mechanization.² His successes were remarkable.

In 1950, Mexico imported over half of its food. Thanks to Borlaug’s efforts to convince farmers there to try his techniques, Mexican food production increased 10-fold by 1970,³ and the country was a net exporter of food. In India and Pakistan, production doubled.⁴ In 1999, the Atlantic Monthly estimated that Borlaug and those he trained and equipped saved the lives of *1 billion* human beings.

Shockingly, the Green Revolution was funded almost entirely by developing countries and private charities (notably the Rockefeller and Ford Foundations),⁵ rather than by the governments of prosperous

nations. At the time, the overwhelming view of academic and political elites in the wealthy countries was that it was already too late to help struggling nations.

Biologist Paul Ehrlich’s 1968 bestseller, “The Population Bomb,” typified this attitude. Ehrlich wrote, “The battle to feed all of humanity is over ... In the 1970s and 1980s hundreds of millions of people will starve to death in spite of any crash programs embarked upon now.” He later said, “I have yet to meet anyone familiar with the situation who thinks India will be self-sufficient in food by 1971,” and “India couldn’t possibly feed two hundred million more people by 1980.” Required reading at many colleges, Ehrlich’s book stated that it was “a fantasy” that India would “ever” feed itself.

Ehrlich, who was wrong about several things,⁶ was unaware of what Norman Borlaug was already in the process of accomplishing.

In the introduction to a 2000 interview with Borlaug, Reason magazine science correspondent Ronald Bailey wrote, “In Pakistan, wheat yields rose from 4.6 million tons in 1965 to 8.4 million in 1970. In India, they rose from 12.3 million tons to 20 million. And the yields continue to increase. Last year [1999], India harvested a record 73.5 million tons of wheat, up 11.5 percent from 1998. Since Ehrlich’s dire predictions in 1968, India’s population has more than doubled, its wheat production has more than tripled, and its economy has grown nine-fold.”⁷

In spite of Ehrlich’s claims, Borlaug helped India to feed itself within a mere five years of the release of “The Population Bomb.” Also around the time of Ehrlich’s pessimistic predictions, Borlaug’s colleagues

at the Consultative Group on International Agricultural Research were spreading Borlaug’s ideas about high-yield rice through Asia, causing another food production explosion. Toward the end of his life, Borlaug was working to institute his agricultural revolution in Africa.

No good deed goes unpunished, so it’s not surprising that Borlaug was attacked by proponents of the new radical environmentalism because Green Revolution farming requires the use of some pesticides and lots of fertilizer. Gregg Easterbrook quotes Borlaug saying the following in the 1990s:

“(Most Western environmentalists) have never experienced the physical sensation of hunger. They do their lobbying from comfortable office suites in Washington or Brussels. If they lived just one month amid the misery of the developing world, as I have for 50 years, they’d be crying out for tractors and fertilizer and irrigation canals and be outraged that fashionable elitists in wealthy nations were trying to deny them these things.”⁸

There’s an old proverb: “He who has bread has many problems. He who has no bread has only one problem.” Today, the talk is all about demands for massive government interventions requiring trillions of dollars to address speculative problems 100 years hence supported by dubious computer models and data. Much less is said about solving real current problems using proven methods that require much smaller sums.

More than 40 years ago, Borlaug wrote, “One of the greatest threats to mankind today is that the world may be choked by an explosively pervading but well camouflaged bureaucracy.”

Some things never change. ■

1 Gregg Easterbrook “The Man Who Defused the ‘Population Bomb,’” *The Wall Street Journal*, Sept. 16, 2009, <http://online.wsj.com/article/SB10001424052970203917304574411382676924044.html> (accessed Jan. 13, 2010).

2 Walt Parks, “What Was the Green Revolution?” <http://wparks.myweb.uga.edu/ppt/green/sld003.htm> (accessed Jan. 13, 2010)

3 Walt Parks, “Mexico’s Wheat Production,” <http://wparks.myweb.uga.edu/ppt/green/sld056.htm> (accessed Jan. 13, 2010).

4 Anwer Iqbal, “Borlaug, father of ‘Green Revolution’, dead,” Dawn Media Group, Sept. 14, 2009, <http://www.dawn.com/wps/wcm/connect/dawn-content-library/dawn/news/sci-tech/09-borlaug-father-of-green-revolution-dead--szh-04> (accessed Jan. 13, 2010).

5 Parks, “What Was the Green Revolution?”

6 Wikipedia, “Simon-Ehrlich_wager,” http://en.wikipedia.org/wiki/Simon-Ehrlich_wager (accessed Jan. 13, 2010).

7 Ronald Bailey, “Billions Served: Norman Borlaug interviewed by Ronald Bailey,” Reason Magazine, April 2000, <http://reason.com/archives/2000/04/01/billions-served-norman-borlaug> (accessed Jan. 13, 2010).

8 Easterbrook, “The Man Who Defused the ‘Population Bomb.’”

CLIMATEGATE

A MichiganScience Symposium

The revelation last November that scientists associated with the Climatic Research Unit at the University of East Anglia hid or destroyed research data and shunned dissenters among their ranks continues to generate controversy. Leaked CRU e-mails from the past decade display what MichiganScience believes is a teachable moment for science students — most notably, how the failure to follow the basic principles of science can result in unsound theories rather than open debate. MichiganScience assembled a distinguished panel to discuss the Climategate scandal and what it means for the future of scientific inquiry, reporting and education.

Climate Science and the Inquisition

By Henry Payne

HISTORICALLY, THERE HAS been tension between church and science, particularly where a religion is endorsed by the state. In the 17th century, Galileo's embrace of Copernicanism defied Catholic Church doctrine that the Earth was at the center of the universe. Galileo's bravery in putting scientific discovery before political consensus won him house arrest under charge of heresy until his death.

Nearly 370 years after Galileo's death, e-mails released from East Anglia University's Climatic Research Unit expose similar tensions between science and, this time, green doctrine.

see Payne continued on Page 8

Climategate's Effect on Students

By Michael Van Beek

CLIMATEGATE IS NO doubt extremely damaging to the scientific community. It casts doubt on the reliability of newly developed scientific knowledge and the scientific method. But before you go burn your science textbooks (those things are expensive), let's reflect on just what this means for students of science and for academic research in general.

For these purposes, it's not really all that important who's right about climate change. We might not ever really know who's right. The debate is much more nuanced than one side being right and the other wrong. There's clearly evidence on both sides. What's important is how we use that different

see Van Beek continued on Page 9

Climategate Shatters Scientific Process

By Paul Chesser

THE FALLOUT FROM Climategate was disturbing enough: suspect adjustments of data, exclusion of dissenting views, illegal destruction of information and intimidation of journal editors. But they all had one ugly common denominator — the corruption of legitimate science.

In early 2009, the Science Council in Great Britain came up with a "new" definition of science: "The pursuit of knowledge and understanding of the natural and social world following a systematic methodology based on evidence." Wikipedia offers this:

"The methods of scientific research include the generation of hypotheses about

see Chesser continued on Page 15

Henry Payne

Since global warming first emerged as a public issue in the late 1980s, its advocates have spoken of its moral and scientific significance. “The scientists are virtually screaming from the rooftops now. The debate is over,” sayeth Al Gore, the public face of global warming. “There’s no longer any debate in the scientific community about this. It’s a moral imperative.”

Gore’s close friend, climatologist James Hansen of NASA, became the face of climate science as Gore’s chief scientific expert. But Hansen has not been content to argue scientific merit and has instead embraced the most radical components of green activism. Like Gore, Hansen compares global warming to the Nazi Holocaust, calling the railroad cars that transport coal “death trains.” Coal, he says, “is the single greatest threat to civilization and all life on our planet.”

Indeed, climatologists have not been shy to embrace the political crusade targeting industries for perceived environmental wrongdoings. University of Michigan professor Henry Pollack, a geologist and contributing author to the United Nation’s global warming report that is the basis of anti-carbon laws, also trains green activists to spread the word of climate crisis on behalf of Gore’s Climate Project.

The intimacy of scientists — who claim to be arbiters of the facts — and politicians on global warming is discomfiting.

Politicians often twist facts for political gain. Gore, for example, was asked in a 2006 interview about the “best way to communicate about global warming and get people motivated. Do you scare people or give them hope?” Gore replied: “[I]n the United States ... nobody is interested in solutions if they don’t think there’s a problem. Given that starting point, I believe it is appropriate

to have an over-representation of factual presentations on how dangerous it is.”

Disturbingly, prominent climatologists like Stanford University’s Stephen Schneider share Gore’s interpretation of truth. “On the one hand, as scientists we are ethically bound to the scientific method,” Schneider told *Discover* magazine in 1989. “On the other hand, we are not just scientists but human beings as well. That, of course, entails getting loads of media coverage. So we have to offer up scary scenarios, make simplified, dramatic statements, and make little mention of any doubts we might have. Each of us has to decide what the right balance is between being effective and being honest.”

Climategate reveals that some scientists have tilted decidedly toward dishonesty, vilifying their critics and manipulating data to “trick” the public and “hide the decline” in global temperatures. Their hardball tactics include marginalizing critics of global warming from scientific journals.

Scientists who question approved climate change dogma risk losing state favor and access to the enormous research dollars government controls. Climatologist Phil Jones, who oversaw the East Anglia climate records, and his colleagues received millions of dollars in climate research funding on top of the main government education grant that underwrites the university.¹

The rush to declare scientific proof of green doctrine and secure related research funds has led to a false cry of consensus.

In fact, as an authoritative review by the Heartland Institute² of two international

1 Robert Mendick, “Climategate’ professor Phil Jones awarded £13 million in research grants,” *Daily Telegraph*, Dec. 5, 2009, <http://www.telegraph.co.uk/earth/copenhagen-climate-change-confe/6735846/Climategate-professor-Phil-Jones-awarded-13-million-in-research-grants.html> (accessed Jan. 14, 2010).

2 Joseph L. Bast and James M. Taylor, “Scientific Consensus on Global Warming: Results of an international

survey shows, there is no consensus on climate change. “The question most people are most keen to ask climate scientists is probably ‘do you agree or disagree that climate change is mostly the result of anthropogenic (manmade) causes?’” according to the review. Summarizing a 2003 poll, Heartland found that slightly more than half (55.8 percent) of climate scientists surveyed agreed, 14.2 percent were unsure and 30 percent disagreed. The survey clearly shows that the debate over why the climate is changing is still underway, with nearly half of climate scientists disagreeing with what is often claimed to be the “consensus” view.

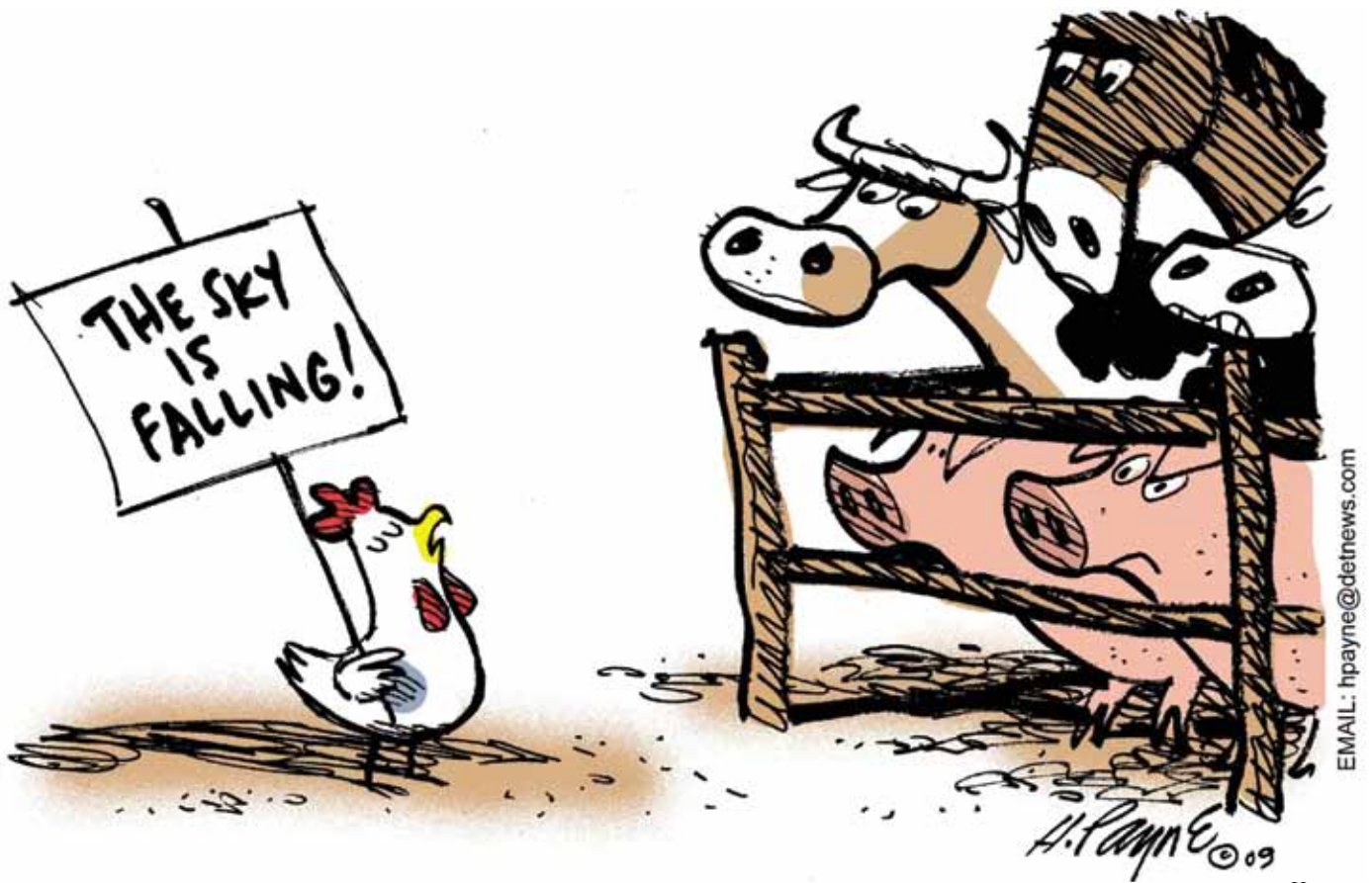
Two weeks after Climategate broke, three of the offending climatologists held a press conference hosted by the Center for American Progress,³ a global warming advocacy group. One of the scientists, Michael Mann of Penn State University, then attacked global warming critics as “a handful of people and organizations that have tried to cloud the debate.”

Clearly, when it comes to understanding how gravely they have damaged their discipline, these “scientists” have learned nothing. ■

Henry Payne is the editorial cartoonist for The Detroit News and a regular contributor to National Review.

survey of climate scientists,” (Chicago: The Heartland Institute, 2007) http://www.heartland.org/custom/semop_policybot/pdf/20861.pdf (accessed Jan. 14, 2010).

3 Stephen Spruiell, “On the Horn with the Warming All-Stars,” *National Review Online*, Dec. 04, 2009, <http://planetgore.nationalreview.com/post/?q=ODZmZWFlMzBkZjQ1OTM2OGZjZGFmZjRmMDIkdDI0OTE=> (accessed Jan. 14, 2010).



"THE EMAILS, HOWEVER, DO NOT ALTER THE SCIENTIFIC CONSENSUS."

Michael Van Beek

evidence to arrive at conclusions, and this is the most troubling part of Climategate.

Science provides us with theories of how the world works based on the best available evidence. It's therefore critical that scientists judge the available evidence clearly and honestly. They must not allow other factors to influence their interpretation and understanding of this evidence, because their conclusions will be used to create the theories that will drive our understanding of the world around us.

Climategate is an example of a group of scientists showing disregard for the importance of judging evidence in this manner. We often assume that scientists naturally honor a sort of Hippocratic Oath for their field, but the reality is that they don't. Their conclusions can be motivated by a number of factors, and the advancement of scientific knowledge may or may not be one of them.

Unfortunately, in the world of research universities, professors from almost all fields have multiple incentives for conducting certain types of research and arriving at particular conclusions. Subsequently, their research and conclusions may or may not advance knowledge and truth.

Many professors avoid this temptation without any problems. Some professors, however, allow these perverse incentives to drive their work, and in the end, what we get is not a broader understanding of science, history, mathematics or anything else. What we get are predetermined conclusions based on an arrangement of bits of evidence that pleases the individuals or organizations that fund the research.

Much of the research conducted in today's universities is funded through government grants. For a variety of reasons, it seems that governments all around the world are very interested in taking action in response to the theory of global warming, as the

recent talks in Copenhagen demonstrate.

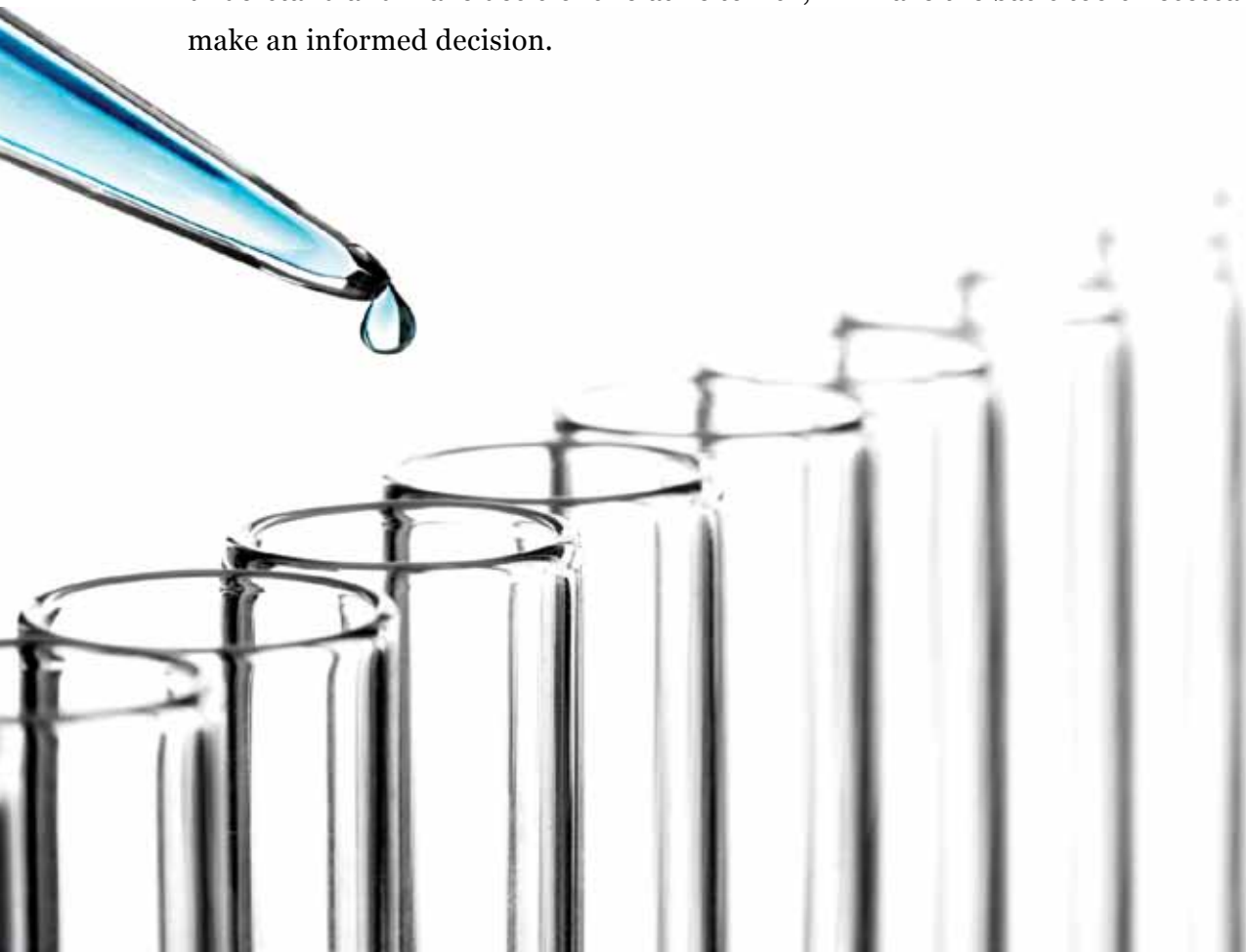
The governmental position on this issue contributes to the disproportionate funding levels for research supporting the theory of global warming as opposed to research questioning its validity. Unfortunately, what drives the politicians in government to support the theory of global warming is not scientific evidence, but the political forces that reward and retain them in their positions of power. It's not surprising, then, to find an incident where scientists purposely attempt to make their research say what they and their funders want it to say, instead of drawing open and honest conclusions based on their best evidence.

Jacob Bronowski, a British mathematician and biologist, once said: "No science is immune to the infection of politics and the corruption of power." Climategate gives yet more credence to Dr. Bronowski's theory. ■

Michael Van Beek is the director of education policy at the Mackinac Center for Public Policy.

RISK ASSESSMENT II

THIS IS THE second in a series of four MichiganScience articles on risk assessment. These articles will be designed to acquaint and provide the reader with information that will allow him or her to understand and evaluate potential risks to human health resulting from exposures to chemicals, including drugs. In other words, this series of papers on risk assessment will not be designed to present the reader with an in-depth treatise on the complexities of risk assessment, but rather will provide a high-level overview of the process. The hope is that enough information will be presented such that the reader, when faced with having to understand and make decisions relative to risk, will have the basic tools necessary to make an informed decision.



IN THE FIRST paper of this series, we discussed some of the fundamental elements of risk assessment. The primary focus of the first article was hazard identification, which is the determination of whether a particular chemical is causally related to a particular adverse health effect. We pointed out that all chemicals, whether they are naturally occurring or man-made, can be toxic and, therefore, have the potential to cause adverse health effects in humans. The dose makes the poison, in other words.

This article introduces two additional steps in the risk assessment process — dose response and exposure assessment. Again, this will not be an in-depth presentation of the complexities of these two steps, but rather a high-level overview.

DOSE RESPONSE

Dose response measures the level of chemical exposure and its impacts. In other words, evaluating the dose-response relationship for a chemical is at the heart of understanding the health risks it may pose.

In order to understand dose and response, we need to understand the conduct of a typical toxicity study. This is how scientists determine at what levels of exposure to a particular chemical it becomes harmful (toxic).

In a toxicity study, multiple groups of experimental animals (ranging from 10 to 60 animals per group) are exposed to or dosed with the chemical.

Because the most common human exposure to chemicals occurs through breathing (inhalation) or eating and drinking (ingestion), these are the two primary routes examined. Very rarely is skin contact evaluated as a route of exposure.

Exposure groups can range in number from three to five. One group is the control

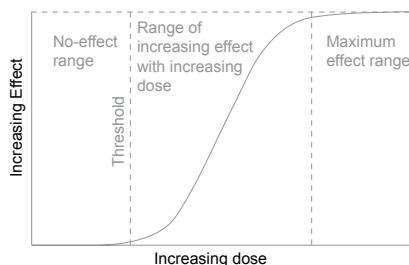
(non-exposure) group, and another group is exposed to the highest dose the animal can tolerate for the duration of the particular study. The effects of the chemical on the experimental animal are monitored throughout the study, including:

- effects on the amount of food eaten,
- changes in body weight,
- outward signs of effects on the neurological system,
- effects on blood parameters, and
- other key measurements.

The chemical's effects on organ systems are calculated at the end of the study by looking at changes in the weight of the organs and examining any microscopic changes that occur.

After the data are collected and analyzed, the results are plotted graphically (as shown below) where the increasing dose is plotted against increasing severity of response. In general, there is a range of doses below which no response or apparent toxicity occurs in the experimental exposure groups. Conversely, there is a higher range of doses over which the toxic properties begin to appear.

Dose-response function with a no-effect region



The exposure dose at which the transition between no apparent toxicity and toxicity occurs is referred to as the threshold dose, or No Observed Effect Level (NOEL).

Implied in this concept, as noted in the first article, is the fact that an individual can be

exposed for a lifetime to a chemical below the threshold and not suffer an adverse effect. It must be noted that even below the threshold, there is likely a sensitive population that responds in some way to the exposure. This is known as inter-individual variation and will be discussed below.

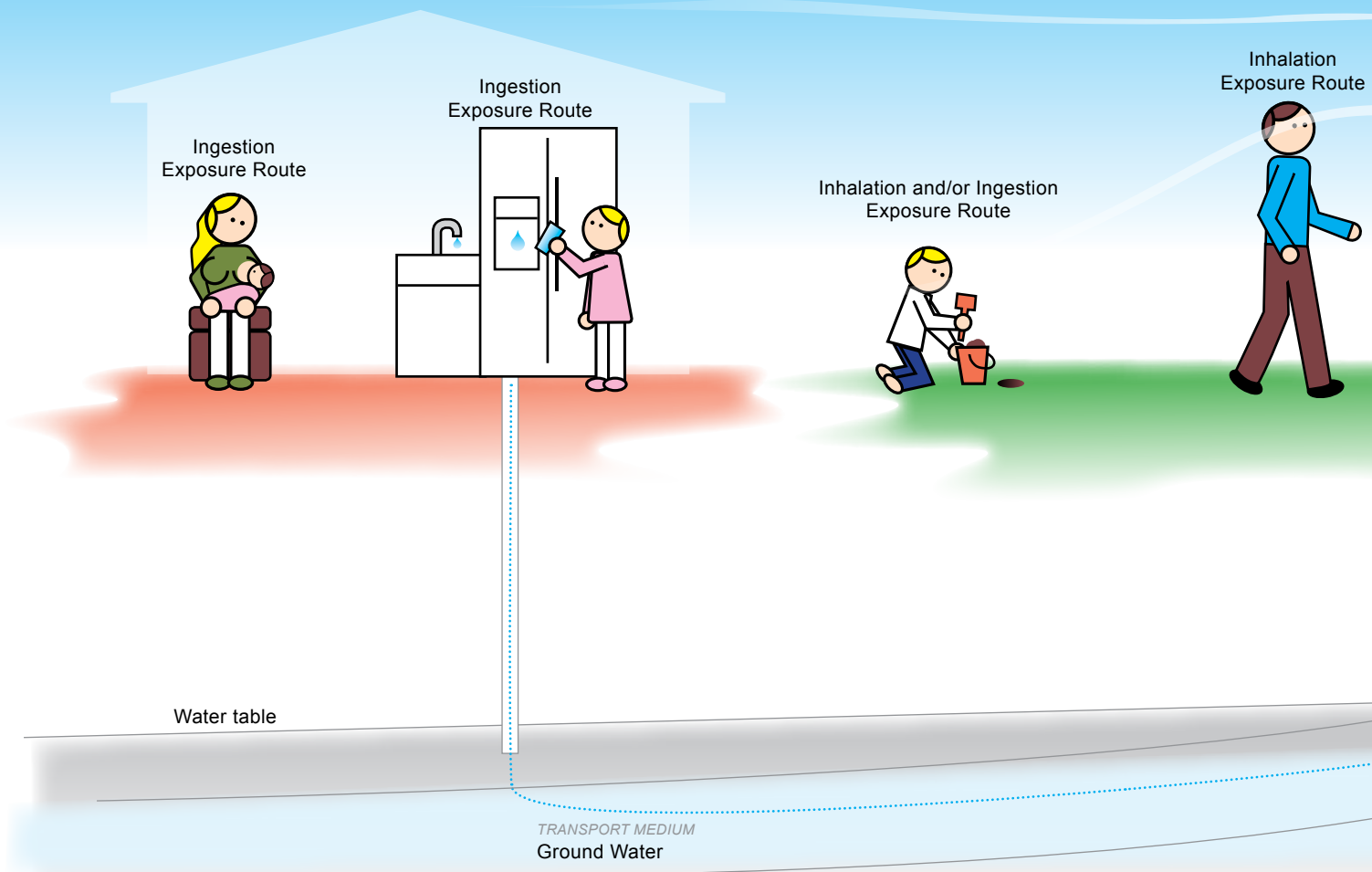
The goal of toxicity studies is to establish a chemical's dose response effects on a specific organ or system, such as the reproductive or central nervous systems. Other studies are designed to assess developmental effects, such as the potential to cause birth defects (teratogens) or the potential to cause cancer (carcinogens).

While most chemicals exhibit a threshold, there are certain classes of compounds for which an argument can be made for no threshold. These compounds (e.g., mutagens and carcinogens) can directly interact with and damage genetic material (DNA) in cells, which can be passed on from one generation of cells to the next. Cells containing such damage are at an increased risk of causing cancer. It should be noted that not all of these cells will become cancerous, but there is an increased probability they will do so. In other words, a single molecule of carcinogen interacting with DNA can potentially lead to cancer. Therefore, it is generally accepted that there is no safe dose or level of exposure for this kind of compound.

DOSE RESPONSE AND RISK ASSESSMENT

There is a complex relationship between dose response and risk assessment:

- Based on the small number of animals used in each dose group in a toxicity study, it is generally accepted that the difference in disease rate or effect needs to be at least 10 percent to be statistically significant.



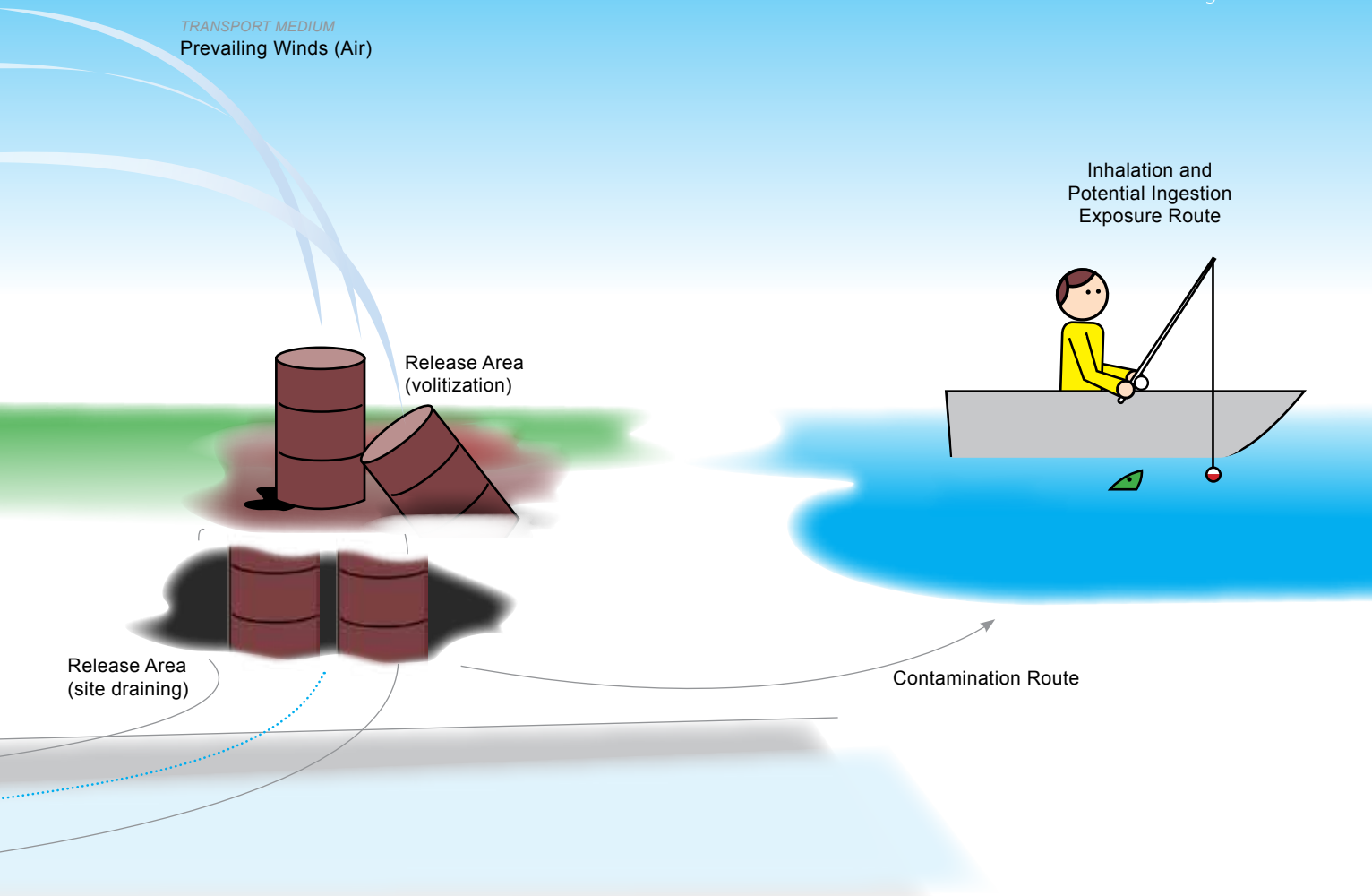
- The dose response can vary significantly depending on whether the chemical was ingested or inhaled, due to differences in absorption in the gastrointestinal tract and lungs.
- The toxicity of a chemical can be due to the actual chemical itself or a metabolite (molecule formed by a chemical reaction between the foreign chemical and the host body) or potentially a combination of both the chemical and the metabolite.
- The external dose is the actual amount to which an organism is exposed, but what toxicologists really want to know is the internal dose or the amount of chemical that is actually delivered to the target tissue. This obviously will depend

LIMONENE IS A hydrocarbon that gets its name from the lemon, as the rind of lemon contains a considerable amount of this chemical compound. Limonene is common in cosmetic products and is used in food manufacturing and some medicines as a flavoring; it also is used as a botanical insecticide. It is added to cleaning products such as hand cleansers to give a lemony fragrance. Limonene is increasingly being used as a solvent for cleaning purposes, such as the removal of oil from machine parts.

The use of limonene has the potential to lead to widespread human exposure. However, limonene was shown to cause increases in incidences of nephropathy, renal hyperplasia and renal tumors in laboratory male rats.

It has been shown in studies that administration of limonene to male rats resulted in the accumulation of a low-molecular-weight protein known as alpha-2u-globulin. The protein build-up is followed by kidney disease and an increased incidence of kidney tumors.

It has been shown that the male rat response to alpha-2u-globulin does not occur in female rats or in other animal species such as mice, nor does it occur in humans. In other words, the carcinogenic response to limonene seen in male rats does not occur in other animal species or humans. It is specific to male rats. Therefore, limonene is not considered carcinogenic to humans. This is a clear example of the potential pitfalls in extrapolating adverse results seen on laboratory animals to humans. ■



on how the chemical is distributed in the body once it is absorbed, how long it stays in the body, how it is metabolized and how it is eliminated from the body (refer to the ADME — absorption, distribution, metabolism and elimination — MichiganScience No. 11, Page 19).

- Two approaches are available to deal with ADME. The first is physiologically based pharmacokinetic modeling. PBPK models are used to predict internal dose at target organs. They consist of a series of equations representing real biological tissues and physiological processes that additionally simulate the ADME of chemicals that enter the body. The advantage of these models is that they rely on the real physiology of the species in question, which makes

them useful for comparing results between different species (interspecies extrapolation). The second approach is biomonitoring, which is the analysis of human body fluids and tissues for purposes of measuring human exposure to chemicals.

In addition to these complexities, there are at least two limitations associated with the use of dose response data in risk assessment. Both of these limitations involve extrapolating data. In essence, this means drawing conclusions about a set of data that cannot be scientifically proven based on information from another data set that has been proven.

For example, toxicologists speak about extrapolating toxicity results obtained in animal experiments to reach conclusions

about possible toxicity in human beings. Since animal studies are generally conducted with high doses in order to elicit and understand the toxicity with a limited number of animals, and since human exposure generally occurs at much lower doses (usually below the threshold), estimating an acceptable risk to human health requires extrapolation from effects seen at high doses to potential effects at lower doses. This provides a level of uncertainty to the risk assessment, since there is potentially a part of the human population that may be extremely sensitive to the potential adverse effects.

The second limitation involves trying to estimate potential effects in humans from studies conducted in animals. In other words, we are faced with interspecies



RISK ASSESSMENT II

extrapolation, which adds another layer of uncertainty when trying to assess the risk to humans. There are many examples of effects that are seen in animals that do not translate to effects in humans (e.g., limonene and renal tumors in rats, see box on Page 12).

From the dose response data, scientists can estimate exposure levels at which adverse responses occur in experimental animals. They also can estimate, at least for chemicals that provoke threshold responses, an exposure level below which most, if not all, humans can be potentially exposed where no adverse effects are expected.

However, there are uncertainties resulting from extrapolations from high dose to low dose and from extrapolating adverse effects seen in animals to humans. The NOEL is the highest dose at which no adverse effects are detected in a hazard identification study. For purposes of a risk assessment, the NOEL is adjusted downward to account for limitations and uncertainties in the available data to arrive at an exposure that is likely to cause no noticeable harmful effects in humans. This is sometimes referred to as reference dose (RfD) or reference concentration (RfC). This approach has been used for years for substances other than those that cause cancer, and it implies that there is a threshold for all other potential adverse affects.

A benchmark dose (BMD) approach has been used as an alternative to address some of the limitations with the use of the NOEL. The BMD is the current approach used by the U.S. Environmental Protection Agency to set an RfD. Unlike a NOEL, the BMD takes into account dose response information by fitting a mathematical model to dose response data. The benchmark dose low (BMDL) is then estimated from this curve.

The BMDL is statistically the 95 percent lower confidence interval of the BMD. Using the BMD approach and then applying appropriate safety or uncertainty factors (see below) to the BMDL to establish a RfD serves as the basis for setting a more scientifically based estimation of a level to protect human health, since this is a conservative estimate of the dose below which humans can be exposed without effect.

In general, the uncertainty factors are used to account for interspecies variation (x10), which allows for extrapolation from animal data to humans and human variability (x10), which takes into account sensitive individuals of the population. The product of these two factors (100) is routinely used in setting what is referred to as the RfD. Therefore, to set the RfD the NOEL or BMDL is divided by 100.

EXPOSURE ASSESSMENT

Once we have established the RfD, we need to gather information for the next step in the risk assessment process. This is the level at which humans are potentially exposed. An exposure assessment is the determination of the extent of human exposure from all sources. It includes a determination of the populations that may be exposed (e.g., worker in an industrial setting, children, consumers, general public, etc.). It also is an estimation of the potential for exposure by a particular pathway such as ingestion, inhalation or skin contact.

Humans are exposed to chemicals through indirect contact in a variety of ways, including air, water, food, soils, dusts, cosmetics products, household products and so on. The pathways of exposure can be as simple as direct contact (cosmetics) and some as complex as a contaminant traveling through the air, depositing in the soil of fields where crops are grown, dissolving in the ground water and taken up through the roots of the crops used to feed livestock that is in turn consumed by humans. If the livestock happen to be cattle, for example, then the contaminant could end up in milk from the cattle. In the case of humans, the contaminant could end up in human breast milk if the mother consumes meat from the cow. Furthermore, to make matters more complex, we have potential exposure from the breathing of air and from human contact with soil and dust. By this time, our contaminant of consideration has passed through and into at least 10 media on its way to human exposure. The illustration on the previous page provides an overview of the potential media and exposure pathways for humans living near a chemically contaminated site.

Since all of the above media contain some level of contaminant, it's important to understand the amount of the chemical in each media as well as the amount of each media to which humans are exposed in order to estimate the external exposure level. This is more often than not a very complex and challenging task.

With the right set of tools such as PBPK modeling and biomonitoring, a somewhat reasonable estimate of the internal dose from the estimation of the external dose may be extrapolated. This estimate of external or internal dose can be compared to the RfD to determine whether we are above or below the RfD and whether there is a risk to human health. Of course, the situation is different for non-threshold carcinogens when one uses the human exposure dose to estimate the probability or incremental increase in risk for a lifetime exposure. Likewise, the process for extrapolating dose response for carcinogens is completely different.

The exposure route is the way the chemical in question moves into the body. Generally, a given medium will result in only one route

of exposure. However, there are cases when a given medium results in multiple routes of exposure. Consider a volatile chemical that is contained in a cosmetic product applied to the skin and some part of the chemical in the product volatilizes into the air. In this case, exposure is by both skin contact and inhalation.

As with other areas of risk assessment, getting a reliable estimate of potential human exposure from environmental and other pathways has its share of uncertainty. Perhaps the major problem is sampling: where to sample, how to take the sample, how to preserve and process the sample, how to analyze the sample, etc.

The obvious goal of sampling the environment is to obtain an accurate representation of the environmental level

of the chemical. In other words, we want to have some confidence that the whole actually is represented by the part taken for analysis. Fortunately, this problem can be dealt with by statisticians who devise sampling strategies that allow scientists to know the degree of confidence of the sampling. The same is true for the analysis of the samples. Quality assurance or quality control programs help ensure the scientific integrity of the analytical results.

In the first article in this series, we discussed the process of hazard identification, which is the first step in a human health risk assessment, and provided basic information related to how the hazards or toxic properties of chemicals are assessed. In this article, we have provided an overview of how dose response

data are generated from the hazard identification data and how these data are used to estimate a safe level of human exposure or, in the case of carcinogens, how to estimate an incremental increase in the risk of developing cancer resulting from a lifetime of exposure to the chemical.

Next, we have shown the complexities of estimating human exposures from a variety of environmental media and the routes by which humans can be exposed. We have presented information now on three of the steps in the risk assessment process. The next article will focus on how the information from the first three steps in the process is used in the risk characterization. The series will conclude with an article on risk management. ■

Paul Chesser

how phenomena work, and experimentation that tests these hypotheses under controlled conditions. Scientists are also expected to publish their information so other scientists can do similar experiments to double-check their conclusions. The results of this process enable better understanding of past events, and better ability to predict future events of the same kind as those that have been tested.”

The revealed e-mails and documents from the Climatic Research Unit at the University of East Anglia undermined every step of the scientific process.

No one knows where the global warming hypothesis started, but rather than test it under controlled conditions, the scientists controlled the conditions to support their hypothesis. One of the best-known Climategate e-mails, from CRU Director Phil Jones, talked about how he used Penn

State University scientist Michael Mann’s “trick” to “hide the decline.” On a chart, Mann cut short records of tree-ring data at the year 1960, because that set showed a temperature decline after that year. Instead, Mann (and Jones) overlaid instrumental data from 1960 onward, making an apples vs. oranges comparison.

Elsewhere, as Marc Sheppard at *American Thinker* discovered,¹ underlying code in programs revealed efforts to “exclude proxy data that demonstrated poor correlations with local temperature.”¹ Simply, the code was an attempt to remove numbers that did not support the scientists’ global warming hypothesis.

Compounding the problem was the fact that CRU scientists — especially

Jones — apparently plotted to withhold or destroy raw data so others could not test the global warming alarmists’ theory. In addition, the research of many skeptical scientists was excluded from publication in peer-reviewed journals, thanks to efforts by the same conspirators. These elites were the gatekeepers of input to the United Nations Intergovernmental Panel on Climate Change reports — which is considered the authoritative source on global warming. Independent double-checking was thwarted.

As a result, this warped “understanding of past events” compromised climate science’s “ability to predict future events.” Climategate showed that global warming concerns were not the product of science but of activism. ■

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¹ Marc Sheppard, “Understanding Climategate’s Hidden Decline,” *American Thinker*, Dec. 6, 2009, http://www.americanthinker.com/2009/12/understanding_climategates_hid.html (accessed Jan. 13, 2010).

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