



CEI UpDate

NOVEMBER/DECEMBER 2002 COMPETITIVE ENTERPRISE INSTITUTE VOLUME 15, NUMBER 9

FDA'S PEDIATRIC RULE GETS OVERRULED

by Sam Kazman

The Food and Drug Administration's Pediatric Rule: for an issue that we've already covered in UpDate twice this year, there's not much to say.

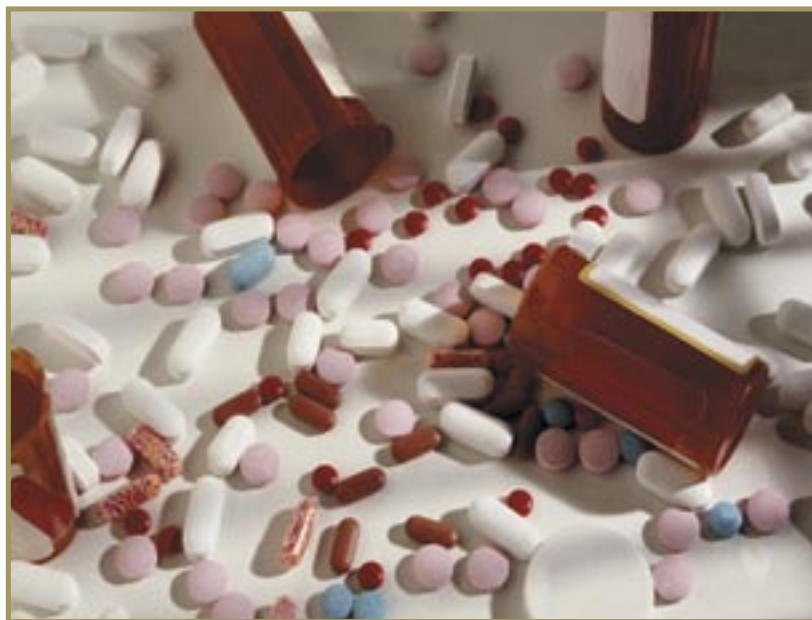
Except that we won.

On October 17th, federal District Court Judge Henry H. Kennedy Jr. held that FDA had no authority to issue its Pediatric Rule. His ruling came in a case brought by the Association of American Physicians and Surgeons, CEI, and Consumer Alert, with pro bono representation provided by the law firm of Wiley Rein and Fielding. Judge Kennedy found that while the federal Food, Drug and Cosmetics Act gave the agency considerable power over the approval and marketing of drugs, it did not enable FDA to impose the radically new testing demands of its Pediatric Rule.

Senator Hillary Clinton called it "a major step backwards for children's health." As you may suspect, there's a little bit more to the story than that.

For starters, there's the fact that the rule

was a major change in the government's drug approval process. Under federal law, a drug maker decides what medical indications to claim for a new drug, and FDA then determines whether the clinical data submitted by the manufacturer support those claims. If the drug is approved, these official indications constitute the drug's "label." However, once a drug is approved doctors are free to use it for any conditions and for any patient populations they consider appropriate. These "off-label" uses are not second-rate medicine; quite often they constitute the best medical practice, especially



when they're based on new medical research completed after the drug's approval. (Most cancer chemotherapy, for example, is off-label; cancer drugs are generally approved for individual use against one specific cancer, but they often are found to be effective against other cancers as well, and to work better in combination with other drugs rather than when used individually.)

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FROM THE PRESIDENT



REASON FOR OPTIMISM? A REPORT FROM JOHANNESBURG

by Fred Smith

Optimism about global environmentalism is rarely warranted. Yet, in the decade between the 1992 Earth Summit in Rio and the 2002 Summit on Sustainable Development in Johannesburg, something went right.

In Rio, the message was Malthusian. The planet was overpopulated. We consumed too many resources, created too many dangerous technologies, and faced a bleak future of ecological disaster. The solution: global governance to curb population, slow consumption, halt technological progress, and vast wealth transfers to fix global inequities.

What changed? In Johannesburg, they discussed poverty. This is progress. It is the admission that there cannot be environmental improvement without giving people a stake in the future. They also addressed the greatest environmental danger facing the world — the need for clean water. This was coupled with the increased awareness that the environmental elite's policies would do little for the poor. With wealth creation topping the Summit's program, environmentalists had to fit their Big Green agenda into an economic framework.

President Bush's decision to not attend the Summit made this possible. Had he been there, delegates would have castigated the U.S. for our consumptive ways and failure to join the ecologically enlightened consensus. His absence forced them to get serious and put greens on the defensive.

Villains included free trade and biotechnology. Trade, it was argued, is a plot to destroy indigenous cultures, luring the poor into a fool's quest for an American lifestyle. Biotechnology was attacked viciously by Indian activist Vandana Shiva, who noted, "[Biotech] is intended to create chemical dependency!" But, the main theme was the world needs more food, grown with less environmental impact. It was an ironic debate to witness on a continent where governments such as Zimbabwe and Zambia pursued policies of mass starvation.

The greatest breakthrough was on clean water — water freed of billions per parts of bacteria, not parts per billion of trace chemicals. The delegates' anti-privatization bias was still evident. They argued water was a "public good" to be provided politically — wealthy nations should underwrite this effort. Energy, they claimed, was too *cheap* — especially in America — but water was too *dear*! Few noted energy privatization ensured sustainable development, while water was experiencing the tragedy of the commons.

Since Rio, a backlash against Western elites' callousness has grown. Population control is increasingly rejected. The conference on Persistent Organic Pollutants rejected an attempt to ban DDT — noting its value in curbing malaria in poor nations. The recent global warming conference in India finally stated the plain truth — that Kyoto would impose major costs on the world while not addressing whatever climate risks might exist. They argued for *Adaptation* — creating the wealth and knowledge that would permit the developing world to adapt to climate change and other risks. And most recently in Chile, the Convention on International Trade (CITES) moved toward allowing South Africa to gain economically from policies that would sustain their elephant populations.

In all these cases, the US sided with the developing world against the European Union and the greens. A realignment is underway — shifting the struggle from one between rich and poor to one between those seeing a world of hope and those fearing change. The United States is regaining its leadership role, confident that a free people ensure that resources are infinite and the future can be better. Progressive Hope vs. Malthusian Gloom — and we're on the right side!

The admission that many things are going right in the developed world, that pollution is dropping and poverty declining, came reluctantly — but it came! There was still too little discussion of national governance changes — specifically the rule of law, property rights, limited government, the democratic process — all are necessary to ensure a sustainable future.

There has been progress since Rio but the environmental movement remains locked in a *demand-sided* approach: problem-solving by restrictions and rigidities. They've adopted a zero-sum view — the only way to make the poor rich is to make the rich poor. Environmentalism has become a reactionary force. As that becomes clearer in coming decades, we can expect a much wealthier **and** cleaner world. And that is a very good thing.

Fred Lee Smith

CEI UpDate

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CEI UpDate is produced 10 times a year by the Competitive Enterprise Institute, a pro-market public interest group dedicated to free enterprise and limited government.

CEI is a non-partisan, non-profit organization incorporated in the District of Columbia and is classified by the IRS as a 501 (c)(3) charity. CEI relies upon contributions from foundations, corporations and individuals for its support. Articles may be reprinted provided they are attributed to CEI.

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ISSN# 1086-3036

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FDA's Pediatric Rule, however, constituted a major alteration in this process. Under the rule, FDA claimed the power to require pediatric testing of drugs labeled for adults, if it found that these drugs were being put to significant off-label use on children. FDA's rationale was that many adult drugs are used by pediatricians without adequate knowledge of their effects in children. The solution, in the agency's view, was to mandate pediatric testing, even though the drug maker did not intend to market the drug for pediatric use. (Bear in mind that the issue here is not the testing of drugs labeled and sold for children. Those must already be tested on children before they

populations, such as the elderly, pregnant women, and immune-compromised patients. And why stop there? Why not impose testing requirements on all significant off-label uses? If researchers find that an arthritis-labeled drug may be useful for diabetes, and if doctors start to use it for that purpose, then why not demand formal clinical trials to assure that the drug is in fact safe and effective for diabetes?

The end result would be drugs tested for all significant special patient groups and all significant uses—drugs tested “1000%.” This is a lovely sounding slogan, but it is also a deadly one. The real end result would be fewer drugs, period, with both children and adults worse off.

Off-label testing is one of those areas where one can make a legitimate case for government incentives. The high cost of the drug approval process means that many off-label uses are too small in scope for companies to seek to put them on-label. Expanding such tests through regulation, rather than by government funding may be politically attractive, but it is the worst approach possible. Like most regulations, its true costs will be hidden. When the result is fewer new medicines, the true costs will be lethal.

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can be approved under current law.) For a drug that had not yet been approved, these pediatric tests could be a condition of approval. For a drug already approved, a company that declined to perform the new tests demanded by FDA could find the drug's approval withdrawn and the drug itself possibly yanked off the market.

In the court's view, this was an illegal expansion of FDA's authority. While agencies are generally given great deference in interpreting their statutes, courts have become more wary of interpretations that expand an agency's power. As Judge Kennedy noted, there is an “unspoken premise that government agencies have a tendency to swell, not shrink, and are likely to have an expansive view of their mission.” Moreover, FDA's “command and control approach” was at odds with the steps that Congress had already taken to encourage pediatric testing through funding and extended market exclusivity.

It's unclear whether FDA will appeal the decision, but the next battle may well take place in Congress, where there are several bills (including one co-sponsored by Hillary Clinton) that would give FDA precisely the authority that the court found lacking. And while the court based its ruling on the fine points of statutory interpretation and administrative law, the congressional battle will be over policy.

A bill that purports to protect our children from unsafe drugs is somewhat difficult to oppose, especially in a time when the pharmaceutical industry, with its supposedly immoral profits and patent rights, is on the verge of demonization. But imposing off-label pediatric tests is a policy that, in the long run, is likely to actually endanger public health. The drug approval process is already incredibly long and expensive, averaging over a decade in length and over \$800 million in costs. A pediatric testing law would increase the complexity of that process. Many potential new adult-labeled drugs might well be shelved if companies now have to consider the added risks of mandatory pediatric tests for off-label uses.

Moreover, with such testing as a precedent, the door would be open to off-label testing requirements for other special

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INTERVIEW WITH DR. RICHARD S. LINDZEN

On the Meaning of Global Warming Claims



Dr. Richard S. Lindzen is the Alfred P. Sloan Professor of Meteorology at the Massachusetts Institute of Technology. He is the author of over 200 books and papers in the scientific literature. He was a lead author on chapter 7 (on physical processes) of the Intergovernmental Panel on Climate Change's (IPCC) Third Assessment Report (2001). One of the world's foremost atmospheric scientists, in 1977, Dr. Lindzen was elected to both the National Academy of Sciences and the American Academy of Arts and Sciences. He has received the Macelwane Medal of the American Geophysical Union and the Meisinger and Charney Awards as well as the Haurwitz Lectureship of the American Meteorological Society. Previously, he worked at the National Center for Atmospheric Research and taught at the University of Chicago and at Harvard University, where he held the Burden Chair in dynamic meteorology. His A.B., S.M., and Ph.D. degrees are from Harvard University.

Lindzen was the keynote speaker at the Cooler Heads Coalition's September 30th congressional briefing entitled

"On The Meaning Of Global Warming Claims." In his presentation, he asserted that despite frequent claims that global warming is a scientifically contentious issue, there really is relatively little disagreement among scientists on a number of basic aspects of the issue. The real problem in public communication is that simple facts about the climate are often presented, and/or perceived, as having ominous implications - even when they don't. Although there is certainly room for skepticism, scientists who note the profound disconnect between the scientific meaning of common statements and the public interpretation, are not being skeptical. They are nonetheless designated as skeptics in order to marginalize their views.

CEI spoke with Dr. Lindzen on the subject of how the findings of scientists are often poorly understood by policymakers and laymen.

CEI: Your thesis statement is that, "It is so far impossible to convincingly relate observed climate change to anthropogenic emissions because we do not fully understand its natural variability" Why is natural variability such a difficult factor for climate modelers to account for?

Lindzen: Natural variability is a statement that even if you don't have man, or sunspots or volcanoes, climate varies. Over the equator, the wind blows from east to west every two years or so. We sort of know why, but no model gets it. We know we have ENSO (El Niño Southern Oscillation), but there aren't very good theories about it. Models tend to do a very bad job of predicting it.

You have all sorts of variations that occur and unless you are looking for a much bigger signal it will be buried in that noise. These are not easy questions. And this is what the science is about, figuring it out.

CEI: You were a lead author of the atmospheric physics section of the IPCC's Third Assessment Report and a peer-reviewer of many of its other sections. How did the version of the "Summary for Policymakers" that was attached to it end up misrepresenting many scientists' intentions?

Lindzen: There are two summaries to the report: the policymaker's summary and the executive summary. They're both in one volume. The executive summary is not terrible. But, the policymaker's summary is not even written by the scientists. The first draft is done by the coordinating lead scientists — there are about 14. Then it is submitted to the IPCC where the government representatives argue each point in its presentation and it is reduced from 1000 pages to roughly 13. It picks statements that it knows mean different things to scientists and to laymen. That was the point of my talk. If you pick and choose selectively and you take advantage of the fact that the public doesn't know how to interpret it or misinterpret it, you don't have to do too much to make a mess.

CEI: Isn't it also the case that the summary itself cannot hope to contain everything that is written in the report?

Lindzen: I think it's fair to say you can't condense. It isn't that it is 1000 pages of sprawling stuff. It's already compacted. But the summary is also kind of random. For instance, the statement in 1995 that the balance of opinion is that there is a discernable impact of man on the climate record — if man had accounted for the entire climate record of the last century, it would mean we don't have a problem. Yet, the statement as phrased sounded ominous to people and they went forward with Kyoto.

CEI: You note that although there are many areas in which scientists working on climate change are in agreement

— and the principles they agree upon may not be well-understood by the public — there are still significant areas of disagreement. Does the specific type of science that an individual researcher specializes in influence his or her view of the policy debate?

Lindzen: It's funding. Plus in a deep sense the environmental movement establishes the grounds for public virtue. If you don't agree with them, you're not virtuous.

CEI: The media made a big deal out of the Bush administration's statements when Dr. Robert Watson failed to obtain reelection as head of the IPCC. What did you think of the decision to replace Watson? Did he allow the mission of the body to be corrupted by politics?

Lindzen: He was politically chosen. He was a Gore choice, not on the basis of his contribution to climate science, which is zero. But because he engineered the ozone issue, his payoff was a job at the World Bank, which isn't exactly a scientific position, but not too many scientific positions pay that kind of salary.

CEI: You state that the most important step that policymakers can take to help scientists is to design "A system of support for science that encourages problem resolution and does not encourage alarmism." Are there steps that Congress can take toward doing this?

Lindzen: There are some suggestions. For example, at present, grants are used to support students. I think students should be supported individually without

reference to grants so that students don't have to follow the money. One of the reasons alarmism is so important, is not that the agencies are so bad or nasty. But if you go before the Senate or the House to defend your program, you give either a complicated description or a simple picture of the science and they scratch their heads. Yet, if you say, "we sent a rocket into space" or "this will cure cancer" they understand it. They understand what they can tell their constituents. The program managers at the agencies have taken their lead from this. They know that their own funds depend on it and they follow up on it. You have to start by realizing what you call accountability is leading to this problem. I don't think Congress wants to give up that.

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The Good, the Bad, AND THE UGLY

The Good

Bush Administration Opposes California's Power Grab Over Fuel Economy Standards

The Department of Justice recently filed a "friend of the court" brief supporting DaimlerChrysler and General Motors in their case against California's "zero emissions vehicles" mandate.

California's Air Resources Board — which had required that ten percent of all vehicles sold in the state be zero-emissions models by 2003 — recently reduced its demands to two percent electric, two percent hybrid, and two percent as "very low emissions" due to poor sales of existing electric models. In determining which standard-gasoline models could be classified as "very low emissions," the board stated that manufacturers that exceed national miles-per-gallon requirements for different classes of cars by 25 to 30 percent could count those vehicles.

However, DaimlerChrysler and General Motors filed suit against the state. They argued its method exceeds the authority the federal government granted to the state in 1967 to impose fuel economy standards on auto emissions. The companies won an injunction in federal court delaying implementation of the rules until 2005. The DOJ is supporting them in their appeals case, which is now being heard by the Ninth Circuit in San Francisco.

In its brief, the DOJ stated that "The Energy Policy and Conservation Act provides that when a federal fuel economy standard is in effect, a state or a political subdivision of a state may not adopt or enforce a law or regulation related to fuel economy standards." It went on to argue that Congress never authorized the states to enact regulations relating to fuel economy standards. More importantly, in defending the DOJ's actions, Transportation Secretary Norm Mineta emphasized that the administration wishes to protect jobs and safety while improving the nation's fuel economy program.

The Bad

Department Of Transportation Not Learning Its Lesson On "Smart" Airbag Mandate

Despite more than 200 deaths caused by airbags over the last decade, the National Highway Traffic and Safety Administration (NHTSA) continues to demand that automakers develop "smart" airbags. It expects manufacturers

to include them in 35 percent of new cars next summer. Companies have warned the agency that sensors, which "smart" airbags use to detect small passengers can be fooled by children buckled in safety seats or adults who shift their weight during a collision. The sensors also don't function well in certain bad weather conditions. In addition, the General Accounting Office warned NHTSA last year that the technology will not be ready by the 2003 deadline.

As CEI General Counsel Sam Kazman has argued in the past: (see UpDate: March 2000) "The basic flaw in the air bag mandate is the notion that it's government's business to force us to protect ourselves. But that flaw is an ethical issue, and ethics are largely banished from today's technocratic regulatory debates."

THE UGLY

Insurance Problems In Texas Continue To Worsen

Of all the industries impacted by the current economic recession, the insurance industry has been one of the hardest hit. Across the nation, an unprecedented increase in claims has left the industry reeling. In response to the increasing number of claims and reduced returns on investments, companies have been forced to cut back coverage and increase premium rates.

According to Fiona Sigalla of the Federal Reserve Bank of Dallas, Texas offers some of the most generous home insurance policy provisions in the country. For example, when a homeowner's roof is damaged during a storm in Texas, it must be fully replaced even if it was in poor condition before being damaged. Although the state is addressing this problem by enabling companies to issue less comprehensive roofing policies, it has not yet offered relief for the skyrocketing number of mold and medical malpractice claims. A recent court ruling forced the state's insurers to cover all of their mold claims, leading them to increase premiums. Medical malpractice suits have increased to the point where over one half of all Texas doctors now have at least one claim pending against them. This led many carriers to stop offering policies to doctors — causing rates to increase by 120 percent since 1999.

This situation underscores the importance of seeking meaningful tort reform to reduce the litigation industry's adverse impact on responsible consumers and their welfare.

President Fred L. Smith, Jr. challenges the wisdom of providing the airline industry with yet another bailout:

Tim O'Brien: Most of the stocks of the big carriers have plummeted far below the post-9/11 lows and analysts seem to agree that without government help some may follow U.S. Airways into bankruptcy. Free-market advocates say that's not a sufficient basis for a bailout.

Fred Smith: What bankruptcy does is merely change the management structure. We don't blow up the airplanes. We don't shoot the pilots. We basically put them under a management team that gives a chance for them to provide more useful, more air-friendly services.

– *Moneyline News Hour (CNNfn)*,
September 23

Senior Policy Analyst Ben Lieberman delivers an “I told you so” after a new report indicating that much of the UN’s alarmism surrounding the ozone hole was unwarranted:

For 30 years, environmental Cassandras have made a number of apocalyptic predictions. None of them, in the fullness of time, has ever come true..

So it is with ozone depletion. While it is true that atmospheric concentrations of chlorofluorocarbons and other chemicals targeted under the Montreal protocol are now declining, this in no way proves that these chemicals posed as serious a threat as originally suggested.

Indeed, the recent UN Environmental Programme/World Meteorological Organisation report and other published evidence indicate that the public health and environmental impact of ozone loss, though real, was considerably exaggerated.

– *Financial Times*, September 28

Senior Fellow Christopher C. Horner warns that efforts by environmentalists and EU officials to foist the Kyoto Protocol upon the World Trade Organization could undermine the WTO’s mission and mandate:

The EU apparently intends to claim that all U.S. goods are impermissibly subsidized by the United States’ refusal to adopt Kyoto-style energy taxes. Last week, Friends of the Earth fired the first shot in this inevitable conflict, demanding the EU apply penalties against energy-intensive U.S. products in retaliation for the United States not going along with Kyoto.

Such a penalty, or alternatively an EU “eco-dumping” suit, would force the pro-growth World Trade Organization to address anti-growth multilateral environmental agreements such as Kyoto. It is not clear whether the WTO, confronted with this conflict, would remain true to its pro-growth mission.

– *National Post*, October 11

Media



Mentions

Warren Brookes Journalism Fellow Hugo Gurdon voices concern that environmentalists’ campaigning against pesticides is exacerbating the spread of West Nile Virus:

The EPA and World Cancer Research Fund are among a wide range of authorities that acknowledge pesticides pose a vanishingly small health risk. You're much, much likelier to get cancer from supposedly healthy foods such as celery, or from your morning cup of coffee, than you are from environmental pesticides...

It should not take a new disease like West Nile to prompt mosquito eradication — we should get rid of them anyway because they're the most irritating creatures in creation. It would be equally wonderful to eradicate the

myths about pesticides — but they've been sprayed with facts so often they've become immune.

– *Washington Times*, October 6

Director of Chemical Risk and Environmental Policy Angela Logomasini exposes the real agenda behind the efforts of Senators John Corzine (D, N.J.) and James Jeffords (I, Vt.) to weaken provisions in the Bush administration’s homeland security proposal:

Angela Logomasini makes a compelling case that Greenpeace, the driving force behind the Corzine-Jeffords measure, has an ulterior motive: the organization sees it as a potent weapon to compel, for ideological reasons, the reduction and eventual elimination of chemicals like chlorine, which are essential to public health. Ms. Logomasini says that, if Corzine-Jeffords passes, Greenpeace is virtually certain to attempt to lobby the EPA to impose restrictions that could lead to reduced use of chlorine in public water. This could well make the water we drink dirtier in the end.

– *Washington Times*, September 16

CEI Receives Clarion Award

The Association for Women in Communications recently recognized CEI with a national Clarion Award for our ongoing public relations campaign on the federal government’s deadly fuel economy standards program. For more information about CEI’s work on this issue, visit the CAFE Café at www.cei.org/pages/cafe.

Trial Lawyers Give Anti-Globalists A Taste Of Lefty Medicine

World Bank/IMF protestors who jammed the streets of downtown DC and broke windows at Citibank and other businesses may not get off with a mere slap on the wrist. *TheAgitator.com* reports that George Washington University law professor (and legendary trial lawyer) John Banzhaf is planning a class-action lawsuit against protestors who inconvenienced commuters. Banzhaf argues, "Trapping innocent people in their cars is not an activity protected by the First Amendment. Regardless of their motives or the validity of their cause, people who criminally interfere with the rights of innocent third parties should be prepared to face the serious financial consequences." Whose streets? Our streets.

Fishy British Motorists Evade High Fuel Taxes

A group of innovators in western Wales was recently caught selling a concoction of methanol and cooking oil from fish 'n chips as a substitute for highly-taxed diesel fuels. *Reuters* reports that the Welsh government responded by assembling a special group of police officers — dubbed the "Frying Squad" — to snuff out violators and levy fines of £500 apiece. As the special blend enables motorists to cut their fuel costs by half, one wonders whether the police's effort will lead to another round of fierce protests over fuel prices around the European continent. Only time will tell.

...END NOTES



Baldwin Boomed By Dairy Belt

Aging actor turned activist darling Alec Baldwin received an icy reception at a recent fundraiser for the Minnesota Democratic-Farmer-Labor Party when angry dairy farmers railed against his participation in People for the Ethical Treatment of Animal's (PETA) campaign to outlaw milk. *Newsmax.com* reports, in addition to sporting signs saying "Deport Baldwin" and "Baldwin and PETA — Udderly Ridiculous," protestors handed out fake airline tickets — a demand that Baldwin make good on his promise to leave the nation when Bush ascended the presidency. Hopefully, other activists are taking note.

Scottish Students Teach PETA A Lesson

Two PETA activists got a surprise on a recent visit to an Aberdeen, Scotland school. Moments into their lecture on the hazards of dairy products, a group of more than a hundred students doused the pair with milk while chanting, "Milk for the Masses." When things got out of hand, police officers escorted the beleaguered activists back to their car. Student Alan Smith observed, "This is a stupid idea. We should be encouraged to drink milk and I certainly won't stop drinking milk just because a man has dressed up as a cow outside my school." No word yet on whether PETA activists are planning to hand out free beer to students on their next trip.



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