

panding its jurisdiction to activities that occur completely within a single state—small-scale research by an academic or a practicing physician testing an innovative therapy.

Many critical reforms recommended by blue-ribbon panels are conspicuously absent. These include reducing the redundancy of regulation of early-stage clinical trials and a binding reciprocity provision that, for example, would limit the duration of FDA review of a new drug to a maximum of, say, 60 days after its approval in the United Kingdom or by the European Medicines Evaluation Agency (thereafter, FDA would have to show cause why the drug should not be marketed in the United States, or it would automatically be approved).

Following Congress's failure to accomplish significant FDA reform, the costs of drug development (already averaging more than \$500 million to bring a single product to market) will continue to rise, fewer drugs will be developed, and market competition will erode. Patients will suffer higher prices and benefit from fewer breakthrough drugs.

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Thumbs Down on Acupuncture

The U.S. National Institutes of Health (NIH) consensus statement on acupuncture (Random Samples, 14 Nov., p. 1231) should not prompt physicians to use acupuncture or to refer patients to acupuncturists.

The panel convened by the NIH, in fact, presented meager conclusions. It announced that there is "clear evidence that needle acupuncture is efficacious for adult postoperative and chemotherapy nausea and vomiting, and probably for the nausea of pregnancy," and that there was "evidence of efficacy for postoperative dental pain." It did not quantify the degree of "efficacy" of needle acupuncture in these conditions, or discuss its actual usefulness.

The nausea of some forms of chemotherapy is severe, but current medications used for its suppression are increasing highly effective and do not present major side effects. Why torment patients just emerging from surgery, or suffering from the effects of chemotherapy, with multiple and repeated needle insertion and manipulation?

The precise cause of nausea of pregnancy is enigmatic. The NIH statement qualified its comments on this point. It did not comment on hyperemesis gravidarum, the real problem, or the possible effects of painful

daily needling of pregnant women over a period of months.

"Postoperative dental pain" is well handled by the brief administration of minor analgesics, which presents minimal risk and is much to be preferred over 20-minute, painful needling.

The panel also points out "there are also studies that do not find efficacy for acupuncture in pain..." and that there is "evidence that acupuncture does not demonstrate efficacy for cessation of smoking and may not be efficacious for other conditions."

In short, it appears that the panel concluded that acupuncture was virtually useless, declared a "victory" as ordered up, and called for more research expenditure to heap on that already wasted.

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Drug Abuse and Therapy

The special section "Frontiers in neuroscience: The science of substance abuse" (3 Oct., p. 45) highlights many of the exciting advances in this field. From molecular neu-



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robiology, to animal behavior, to control of human behavior, our knowledge and understanding are being pushed forward rapidly. Unfortunately, those who deliver services to their clients who have alcohol or drug dependency are rapidly falling behind.

In his article "A range of research-based pharmacotherapies for addiction" (p. 66), Charles P. O'Brien looks forward to new drug developments, but notes that the use of Revia (naltrexone hydrochloride) has languished even though it has been proved safe and effective (1). Recently, a director of a county mental health substance abuse program presented to our study group changes he has made to his program. When asked whether he was prescribing naltrexone to any of his alcohol-dependent patients, his response was, "We have not yet decided who the appropriate patient is to receive Revia." I maintained that any patient who has relapsed within a year of completing treatment is the appropriate patient and that it is unethical *not* to use naltrexone in these patients.

During the 1996 Annual Meeting of the Society for Neuroscience, I saw many poster presentations by pharmaceutical industry scientists describing their latest novel antipsychotic and anti-anxiety drugs. I asked everyone whether there was an interest in test-

ing their lead drugs in animal models for treatment of alcoholism or drug addictions. Not one stated that their company had a proprietary interest in this area. Even Pharmacia-Upjohn, which may have the most promising lead candidate drug (2), has apparently dropped research in this area.

If there is no market, then the companies are not interested in developing new compounds or investing in clinical trials. Even the European-based companies are losing interest in this area.

I do not believe that the National Institute on Drug Abuse can or should become a pharmaceutical research and development institution, complete with a marketing arm. We need a major change in the attitude of those delivering treatment toward novel approaches to treatment. Otherwise, all of the wonderful and exciting research being done will become just so much esoterica.

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Response: McMillen makes an excellent point that was also mentioned in my article and discussed in detail in a recent Institute of Medicine (IOM) report (1).

There are two widely held, incorrect sets of belief. The first, held by clinicians, is that addiction is a social problem that should not be treated with a medication. Therapeutic drugs and addicting drugs are lumped together in their minds in this "drug free" approach. Medications that have been found to help in addictive disorders are to be avoided because they are a "crutch."

The second set of beliefs, held by pharmaceutical companies, is that drug addicts are not dependable participants in clinical trials, that the market for medications in the addiction area is not large, and that the potential for third-party payments is uncertain. These issues are discussed at length in the IOM paper (1).

There is some reason for optimism. Revia, used for the treatment of alcoholism, has been steadily gaining in sales over the past 2 years. Although the manufacturer is no longer actively promoting it (because the drug becomes generic in 1998), Revia appears to be selling itself because of its efficacy when prescribed and the accumulation of confirmatory published clinical data. Another treatment for alcoholism, acampro-

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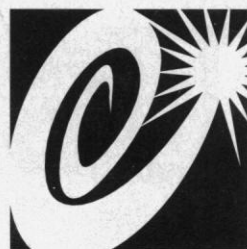
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sate, is currently in clinical trials in the United States, and several pharmaceutical companies are actively developing other medications to be placed in clinical trials for addictive disorders. There are still many hurdles to overcome, but there is progress.

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Ancient Sharks and Rays

The item "Shark and ray extinctions" by Ann Simon Moffat (Research News, 31 Oct., p. 801) featured a discussion on a portion of our work on Late Cretaceous (Maastrichtian) vertebrates found in the Fox Hills Formation and Paleocene Cannonball Formation of North Dakota, as reported at the recent Society of Vertebrate Paleontology meeting (1). Moffat discussed the Cretaceous-Tertiary (K-T) boundary extinctions as demonstrated by cartilaginous fish faunas of the Western Interior Seaway, and we would like to clarify some aspects of our research that she mentioned.

We have studied more than 40 sites in the Fox Hills Formation and 70 sites in the Cannonball Formation. There is little disagreement that the 22 species of sharks and rays we found in the Fox Hills were extinct by the Paleocene; rather, the issue may be the rapidity of that extinction. As suggested by the comments attributed to J. David Archibald, the K-T boundary section is not complete because units of terrestrial Hell Creek and Ludlow Formations intervene in North Dakota, where we are working. The K-T boundary occurs within this interval of regression (2), making precise correlation between the marine cartilaginous fish faunas and the terrestrial vertebrate faunas difficult.

These facies, although complex, are well understood paleoenvironmentally. Similar depositional conditions created both the Fox Hills and Cannonball Formations. There is little likelihood the faunal changes we document resulted from environmental changes, as suggested by Archibald, for we have sampled similar suites of nearshore marine facies on each side of the K-T boundary. Habitat-sensitive mollusk faunas confirm similar origins of most Fox Hills and Cannonball facies (3). Furthermore, given the similarity

of habitats sampled, there is little likelihood that our data result from habitat displacement rather than biological extinction. Significant species-level change in cartilaginous fish faunas occurred across the K-T boundary in the Williston Basin, and apparently globally, at a rate not yet determined.

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Corrections and Clarifications

■ In the "Association Affairs" essay "Conversation with the community: AAAS at the millennium" (19 Dec., p. 2066), two co-authors, William T. Golden and Richard S. Nicholson, were inadvertently omitted. The authors should have been listed as follows: "Sheila Jasanoff, Rita Colwell, Mildred S. Dresselhaus, William T. Golden, Robert D. Goldman, M. R. C. Greenwood, Alice S. Huang, William Lester, Simon A. Levin, Marcia C. Linn, Jane Lubchenco, Richard S. Nicholson, Michael J. Novacek, Anna C. Roosevelt, Jean E. Taylor, Nancy Wexler."

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