

OMB CHALLENGES EPA

# WHITE HOUSE JOINS THE REGULATION DISPUTE

WASHINGTON, D.C.—After ignoring the biotechnology industry since Ronald Reagan became president three and a half years ago, the White House has now joined the dispute over how it should be regulated.

The Office of Management and Budget (OMB), the White House's watchdog for regulatory and budgetary affairs, has stepped into the fray with an opinion on where to rest regulatory authority. In a memo to the high-level Cabinet Council on Economic Affairs, OMB's Christopher DeMuth argued that the Council, not the Environmental Protection Agency, should decide whether and when to regulate the biotechnology industry. OMB involvement means that the industry is once again uncertain where it stands in Washington, or how the inter-agency squabble will resolve itself.

EPA has spent the last 18 months gearing up to oversee biotechnology, including confirming internally that it had the legal authority to regulate genetically engineered products as new chemicals under the Toxic Substances Control Act (TSCA). DeMuth's memo challenged this authority, declaring that DNA is not a new chemical. OMB prefers the present system, under which the Recombinant DNA Advisory Committee of the National Institutes of Health establishes voluntary guidelines for industry. EPA has suspended its plans to publish a "notice of proposed rulemaking" in the *Federal Register* this month.

The response to OMB's involvement has been mixed. Some observers believe OMB is imposing its will unnecessarily on EPA and several other federal agencies, such as the

Food and Drug Administration and the Department of Agriculture—agencies that on their own were sorting out overlapping jurisdictions. Others think OMB is stepping in as a power broker to resolve inter-agency conflicts that have been smoldering for months and that would continue to smolder without OMB direction.

At the least, OMB's involvement is likely to stall regulation for several months longer. OMB's DeMuth is strongly against regulation. He has made a career in Washington working to deregulate industries or to create incentives for voluntary compliance with such goals as clean air and water.

Furthermore, OMB has put on hold the activities of the little-known Interagency Risk Management Council (IRMC), which draws its members from EPA, Agriculture, and—

## STOCK PRICES OF SELECTED BIOTECHNOLOGY SPECIALTY FIRMS

	Price April 15	Price May 11	Percent Change	52 Week Hi-Low	Market Capitalization in \$ millions (stock price × number of shares outstanding)
<b>Companies Emphasizing Recombinant DNA Technology</b>					
Advanced Genetic Sciences	4 <sup>3</sup> / <sub>4</sub>	5 <sup>3</sup> / <sub>4</sub>	+21	14 <sup>3</sup> / <sub>4</sub> –3 <sup>1</sup> / <sub>4</sub>	63
*Amgen	5 <sup>3</sup> / <sub>8</sub>	5	-7	18–4 <sup>3</sup> / <sub>8</sub>	50
*Bio Logicals	1 <sup>5</sup> / <sub>8</sub>	1 <sup>3</sup> / <sub>4</sub>	+8	6 <sup>1</sup> / <sub>2</sub> –1 <sup>1</sup> / <sub>4</sub>	10
*Biogen	12 <sup>1</sup> / <sub>4</sub>	11	-10	19 <sup>3</sup> / <sub>4</sub> –9 <sup>3</sup> / <sub>4</sub>	204
*Biotech Research Labs	7 <sup>1</sup> / <sub>2</sub>	9 <sup>3</sup> / <sub>4</sub>	+30	21 <sup>1</sup> / <sub>2</sub> –6 <sup>3</sup> / <sub>4</sub>	50
*Biotechnica International	6 <sup>1</sup> / <sub>4</sub>	6	-4	17 <sup>1</sup> / <sub>4</sub> –5 <sup>1</sup> / <sub>4</sub>	23
Biotechnology General	6	6	0	10–5	33
California Biotechnology	10	10	0	14–10	48
*Cetus	10 <sup>3</sup> / <sub>4</sub>	11 <sup>3</sup> / <sub>8</sub>	+6	19–10 <sup>1</sup> / <sub>4</sub>	250
Chiron	5 <sup>1</sup> / <sub>4</sub>	5 <sup>3</sup> / <sub>4</sub>	+10	12 <sup>1</sup> / <sub>4</sub> –5	39
*Collaborative Research	7 <sup>1</sup> / <sub>2</sub>	6 <sup>7</sup> / <sub>8</sub>	-8	15 <sup>1</sup> / <sub>2</sub> –6 <sup>1</sup> / <sub>8</sub>	68
CooperBiomedical	7	7 <sup>3</sup> / <sub>4</sub>	+11	11 <sup>3</sup> / <sub>8</sub> –5	138
*Enzo Biochem	17 <sup>1</sup> / <sub>2</sub>	15 <sup>1</sup> / <sub>2</sub>	-11	34 <sup>1</sup> / <sub>4</sub> –13	135
*Genentech	34 <sup>3</sup> / <sub>4</sub>	33 <sup>3</sup> / <sub>4</sub>	-3	49 <sup>3</sup> / <sub>4</sub> –25 <sup>7</sup> / <sub>8</sub>	479
*Genex	11 <sup>1</sup> / <sub>2</sub>	10	-13	23 <sup>1</sup> / <sub>4</sub> –9 <sup>3</sup> / <sub>8</sub>	128
Integrated Genetics	3 <sup>3</sup> / <sub>4</sub>	4	+7	13–3 <sup>1</sup> / <sub>2</sub>	33
*Molecular Genetics	13	13	0	23–10 <sup>7</sup> / <sub>8</sub>	79
<b>Companies Emphasizing Antibody Production Technologies</b>					
*Bio-Response	12 <sup>3</sup> / <sub>4</sub>	12 <sup>3</sup> / <sub>8</sub>	-1	16 <sup>1</sup> / <sub>8</sub> –9 <sup>1</sup> / <sub>8</sub>	100
*Cambridge BioScience	2 <sup>3</sup> / <sub>8</sub>	3 <sup>3</sup> / <sub>4</sub>	+43	17 <sup>1</sup> / <sub>4</sub> –2 <sup>1</sup> / <sub>4</sub>	15
*Centocor	10 <sup>1</sup> / <sub>2</sub>	10 <sup>1</sup> / <sub>4</sub>	-2	19 <sup>1</sup> / <sub>4</sub> –8 <sup>3</sup> / <sub>4</sub>	72
*Damon Biotech	7	7 <sup>1</sup> / <sub>2</sub>	+7	17 <sup>1</sup> / <sub>2</sub> –6	144
*Genetic Systems	6	7	+17	17 <sup>3</sup> / <sub>4</sub> –5 <sup>3</sup> / <sub>4</sub>	138
*Hybritech	13 <sup>1</sup> / <sub>2</sub>	16 <sup>1</sup> / <sub>4</sub>	+20	31–12 <sup>1</sup> / <sub>4</sub>	167
*Monoclonal Antibodies	10 <sup>1</sup> / <sub>4</sub>	12	+17	21 <sup>1</sup> / <sub>2</sub> –10	29
*Summa Medical	4 <sup>3</sup> / <sub>4</sub>	4 <sup>3</sup> / <sub>8</sub>	-8	18 <sup>3</sup> / <sub>8</sub> –3 <sup>3</sup> / <sub>8</sub>	34
<b>Companies Emphasizing Other Products or Biotechnologies</b>					
Applied Biosystems	17	18 <sup>3</sup> / <sub>4</sub>	+10	21 <sup>1</sup> / <sub>2</sub> –13	90
Cell Products	10 <sup>3</sup> / <sub>4</sub>	9 <sup>3</sup> / <sub>4</sub>	-9	24–7 <sup>3</sup> / <sub>4</sub>	41
*Genetic Engineering Inc.	4	4	0	10 <sup>7</sup> / <sub>8</sub> –3 <sup>3</sup> / <sub>8</sub>	10
*Immunix	5 <sup>1</sup> / <sub>2</sub>	6 <sup>1</sup> / <sub>4</sub>	+14	13 <sup>3</sup> / <sub>4</sub> –4 <sup>7</sup> / <sub>8</sub>	36
*Interferon Sciences	3 <sup>1</sup> / <sub>2</sub>	3 <sup>3</sup> / <sub>4</sub>	+7	11–3 <sup>1</sup> / <sub>4</sub>	15
*Ribi Immunochem	7 <sup>1</sup> / <sub>2</sub>	7 <sup>1</sup> / <sub>2</sub>	0	15 <sup>1</sup> / <sub>2</sub> –5 <sup>3</sup> / <sub>4</sub>	22
Vega Biotechnologies	3 <sup>3</sup> / <sub>8</sub>	4	+19	11 <sup>1</sup> / <sub>2</sub> –3	11

The BIO/TECHNOLOGY Index of Specialty Firms stands at 678 as of May 11, down from 666 on April 15, 1984. The Index is composed of the 23 companies in the chart that are marked by an asterisk. For a more complete explanation of the Index, see BIO/TECHNOLOGY 1:536.