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PRODUCT STEWARDSHIP & SUSTAINABILITY REPORT

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Pharma Product Stewardship Becomes Real

By David B. Weinberg

The U.S. Supreme Court's May 26, 2015 decision not to reconsider the pharmaceutical industry's challenge to Alameda County, California's unwanted medicine stewardship ordinance[1] is about to have a real-world, practical effect. In February 2015, Alameda County's Department of Environmental Health approved one multiparty plan and one single company plan to comply with that ordinance, but the full impact of the multiparty plan is not scheduled before February 2016. In the meantime, however, the stage has been set for the implementation of a different multiparty "standard" stewardship plan in King County, Washington (Seattle) a month earlier.[2]

Although the case that reached the Supreme Court challenged an ordinance adopted in Alameda County in 2012,[3] King County also has been moving aggressively to implement a used drug program. Its ordinance was adopted in 2013. In both jurisdictions, drug manufacturers must bear the cost of collecting and destroying unwanted pharmaceuticals.

San Francisco, San Mateo, Santa Clara, and Marin counties also have adopted similar ordinances since the Ninth Circuit's decision.[4] In addition, at least half a dozen other California jurisdictions, including Los Angeles and San Diego, reportedly are studying proposals, and similar ordinances are expected to be presented elsewhere around the nation.

However, "product stewardship" in this arena presents a unique challenge. Few worry about the

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Manufacturers and Retailers' Free Speech Rights Remain in Flux

By Megan L. Brown and Craig G. Fansler

The question of whether the government may require companies to include government-preferred messaging and information in their communications remains hot and unresolved. A D.C. Circuit decision last month reached the opposite result as a year-earlier *en banc* decision from the same court. This highlights the uncertainty facing manufacturers, retailers, and advertisers. Ultimately, Supreme Court attention appears likely to be necessary. Congress, states, and agencies mandate all sorts of disclosures, from securities filing requirements to nutritional labeling. Some regimes are uncontroversial and unchallenged. Others may—and often are intended to—carry a stigma or alter consumer preferences. Litigation over meat

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IEC to Develop Battery Marking Standard

By Saskia Mooney

On August 21, 2015, the International Electrotechnical Commission Technical Committee 21 (IEC TC 21) approved a New Proposal (NP) 21/859/NP to develop a standardized international battery marking standard. This action comes in response to increasing concerns from secondary lead smelters about the inclusion in their input stream of lithium-ion batteries. Smelter processing of the lithium ion batteries can produce explosions. The growing availability of lithium ion batteries in the same "form factors" as lead-acid batteries has exacerbated this concern.

Overcoming these concerns no doubt will require a number of steps, of which last month's IEC action is only one. The hope is that, with a sufficient

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security of collected used soda bottles, batteries, carpets, or paints. But collected drugs are another matter. The Drug Enforcement Agency eased the way to implementation in September 2014, when it adopted a new rule governing collection and disposal of controlled substances.[5] Among other things, that rule authorized retail pharmacies and others to become "authorized collectors" of unwanted drugs, subject to a number of security requirements, and extended the time by which drug destruction is required to allow implementation of reverse-distribution systems. Another potential impediment to implementation is expected to be overcome within the next few weeks, with EPA finalization of an amendment to the Resource Conservation and Recovery Act (RCRA) "universal waste rule" that simplifies handling of used drugs that qualify as "hazardous wastes."[6]

The Alameda Ordinance

Alameda's ordinance mandates operation (and funding) of a program by "producers" to collect and destroy unwanted prescription drugs ("covered drugs").[7] "Producers" are defined as manufacturers of the drugs who sell, offer to sell, or distribute the drug in Alameda County, brand or trademark licensee or owners, or (in the absence of a person who falls into the two prior categories) the person who brings the drug into the county for sale or distribution.[8] Excluded, however, are retailers of store-brand products covered by the product's manufacturer and pharmacists.[9]

The mandated program(s) must accept all used covered drugs, regardless of who manufactured them, without charge, and arrange for the proper destruction of the drugs.[10] It authorizes both mail-back and retail collection, as well as collection at law enforcement agencies, and requires a substantial public education program.[11]

The King County Ordinance

King County's ordinance similarly imposes on "producers" the obligation to participate in (and fund) one or more collection and destruction programs. Unlike Alameda's ordinance, however, it applies to

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Manufacturers and Retailers' Free Speech Rights Remain in Flux *continued from page 1*

labeling and a requirement that public companies characterize their products' use of "conflict minerals" shows that government and the private sector will continue to clash over mandated speech.

Recent D.C. Circuit Cases Have Approached Government-Mandated Disclosures Differently

Upholding USDA's Meat Labeling Rule

The first of the recent cases, *American Meat Institute v. United States Department of Agriculture*, decided *en banc* over a year ago, upheld a Department of Agriculture regulation that required disclosure on meat-product labels of the country where individual animals were raised and slaughtered. Prior cases in the D.C. Circuit had upheld government regulation of misleading advertisements. But in *American Meat*, the government conceded the labels were not misleading. Instead, USDA claimed that consumer interest in country-of-origin information justified mandated disclosures.[1]

The legal issue presented was whether a lower standard of review—which makes it relatively easy for the government to defend a rule—should apply. In the leading precedent, *Zauderer v. Office of Disciplinary Counsel*,[2] the Supreme Court had applied the lower standard in upholding a state law that had compelled attorneys who advertise that fees are contingent to also disclose that costs are not—that is, the clients might have to pay costs, even if they lose.

To be sure, the First Amendment guarantees the right to speak or stay silent.[3] But in *Zauderer*, the Court found that a company's interest in not carrying "factual and uncontroversial" corrective disclosures was minimal, and such disclosures could be required in advertisements to prevent consumer deception.[4]

From that simple conclusion, things got more complicated. As governments have embraced varied "disclosure" obligations—from calorie counts to environmental regulation and graphic tobacco warnings—courts have struggled to identify when it is proper to apply *Zauderer*. Should it govern and effectively bless any potentially useful "commercial disclosures," as some would have it, or be limited to disclosures aimed at correcting deceptive advertising? The alternative to *Zauderer* is a more demanding scrutiny, requiring the government to prove a substantial government interest for

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both unwanted prescription and unwanted over-the-counter "drugs" and expressly anticipates both "standard plans" and "individual plans" to collect. "Producers" are defined as manufacturers "engaged in the manufacture of a covered drug sold in or into King County, including a brand-name or generic drug," but with exclusions for retailers' store-brand products covered by the product's manufacturer, compounding pharmacists, and wholesalers.[12] "Drugs" is also broadly defined, and includes not only articles recognized by several authorities as pharmaceuticals, but also "substances intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in humans or other (sic) animals" and "substances, other than food, intended to affect the structure or any function of the body of humans or other (sic) animals." However, medical devices and their components are excluded.[13]

Plans must provide "convenient collection" opportunities for all King County residents, potentially including secure collection at retail pharmacies and law enforcement agencies, periodic collection events and a mail-back program, as well as secure transportation of collected materials to appropriate disposal facilities and destruction of the collected drugs.[14] They must also describe public education and promotional efforts and short- and long-term goals for collection amounts, education, and promotion.[15]

Approved Alameda County Plans

Two plans have been approved in Alameda County. One, submitted by Exelixis, Inc., is narrowly limited to a collection of a single, newly developed drug currently being used in Alameda County by only one patient. The other is a multi-party plan developed by Alameda MED-Project LLC, a company established by the pharmaceutical industry's Pharmaceutical Product Stewardship Working Group.

The Alameda MED-Project plan pointed to ambiguities in the DEA's September 2014 regulation to support the need for a one-year initial implementation period that focused on collection at law enforcement agencies and a dozen public take-back events, with retail pharmacy collection to be implemented in the second year, if sanctioned by DEA. The project's first annual report, due in February 2016, is expected to more fully describe how that program has been working and will be developed.

Pending King County Plans

The King County ordinance provides an iterative process for plan development and approval. Two entities have pursued approval as the standard plan: the King County MED-Project and Return Meds LLC. No other proposals were submitted. Both sponsors' original submissions were rejected, but both also have submitted revised plans.

The King County MED-Project is an analogue to Alameda MED-Project, another limited liability company established by the Pharmaceutical Product Stewardship Working Group. Return Meds LLC is a wholly-owned subsidiary of Call2Recycle, Inc., a not-for-profit company established more than two decades ago by battery manufacturers that operates a highly-successful used battery stewardship program in the U.S. and Canada. That program originally handled only used rechargeable batteries, but in recent years has expanded to cover used primary batteries in some jurisdictions.

Both plans propose placing collection kiosks in a number of publicly-accessible locations (retail pharmacies and law enforcement agencies), sponsorship of take-back events and operation of mail-back programs, and both include provisions intended to meet other requirements of the ordinance. The Return Meds proposal appears to be somewhat more ambitious, however. For example, it identifies 112 confirmed retail pharmacy collection locations and ongoing efforts to recruit others. For its part, King County MED-Project's plan says it will "initially target approximately 30 drop-off sites, expanding to approximately 65 sites, and ultimately targeting approximately 92 sites."[16] However, King County MED Project commits itself to up to 24 take-back events (presumably annually) to supplement drop-off site collections, while Return Meds appears to view events as a stop-gap until a comprehensive collection network is established.

What Happens Next?

The next developments in Alameda County should come in early 2016, after Alameda MED-Project submits its first annual report.

There may be earlier activity in King County, however. The King County Department of Public Health is committed to acting on the two proposals by October 10, and could do so earlier. And both plans seek approval as "the" standard plan. If only

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one is approved, all producers will be required to support it, unless the sponsors of the rejected plan revise it to meet whatever deficiencies justified the Department's rejection. If the rejected plan is then subsequently approved, the Department will then treat it as an "independent" plan.

If both are approved, one presumably will be approved as the "standard plan" and the other as an "independent plan," but this is uncertain. It seems most likely that, in these circumstances, the King Count MED-Project plan would be approved as the standard plan, since it appears to be supported by a substantially larger number of producers than the Return Meds plan. But the decision rests with the Department of Public Health.

If both plans are approved, however, and both submitters move to implement their programs—regardless of which plan is denominated as the "standard plan" and which as "independent"—an interesting situation will arise. There presumably will be two parallel collection and mail-in networks put in place, and a practical need for cooperation on public collection events. Inevitably, however, each network will collect used drugs that originated from sponsors of the other network, and incur the resultant costs. King County's ordinance does not address the question of how, if at all, cross-reimbursements could be arranged.

In this respect, this ordinance contrasts dramatically with Vermont's 2014 used primary battery stewardship statute, H.B. 695.[17] That statute includes both a cross-reimbursement process and a private right of action with which one program can enforce it against another, as well as against producers who are sponsoring no program whatsoever. That provision no doubt reflects the longer experience of the battery industry with product stewardship mandates. Whether future used drug ordinances pick up a similar element may well be influenced by the forthcoming experience in Seattle.

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[1]*Pharm. Research & Mfrs. of Am. v. Cnty. of Alameda, Cal.*, 135 S. Ct. 2348 (2015).

[2]King Cnty. Bd. of Health R. & Reg. 13-03.1.

[3]Alameda Cnty. Health & Safety Code § 6.53.10.

[4]*Pharm. Research & Mfrs. of Am. v. Cnty. of Alameda*, 768 F.3d 1037 (9th Cir. 2014).

[5]79 Fed. Reg. 53,520 (September 9, 2014).

[6]*See* Proposed Rule, Amendment to the Universal Waste Rule: Addition of Pharmaceuticals, 73 Fed. Reg. 73,520 (Dec. 2, 2008).

[7]Alameda Cnty. Health & Safety Code § 6.53.030(3).

[8]*Id.* § 6.53.030(14).

[9]*Id.*

[10]*Id.* § 6.53.050(A)(1).

[11]*Id.* § 6.53.050 (5), (11), (12).

[12]King Cnty. Bd. of Health R. & Reg. 13-03.1 § 5(P).

[13]*Id.* § 5(F).

[14]*Id.* §§ 6, 7.

[15]*Id.* § 7.

[16]King County MED-Project Plan, p.10.

[17]Vt. Stat. Ann. tit. 10, §§ 7581 *et seq.* (2015).

education campaign about the significance of chemistry-specific labels, collectors who prepare pallets of lead-acid batteries for shipment to smelters can be convinced to avoid including lithium ions in their shipments. With obvious markings, it should also be easier for scrap dealers and less sophisticated collectors to avoid providing lithium ions to smelters.

The immediate proposal is only the first step in the IEC process, however: it starts the development of a standard. The concept is to include two key elements in all battery labels: (1) a label background color coding (grey for lead, aqua blue for lithium, etc.); and (2) the marking of the battery with the three chasing arrows recycling symbol and a chemical symbol (Pb, Li, Li-ion, Li-metal, etc.). The development process will be complicated by the need to conform any mandatory labeling with existing requirements in the United States, European Union, and elsewhere. Seventeen countries—including the United States—voted in the affirmative to move forward with development of a new standard.

The Working Group will hold its first meeting late September in Brussels. The current target to circulate a first stage document (Committee Draft) for international review and comment is aggressive: December 2015. The IEC expects to have a final document ready for approval at the end of 2017.

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Summer Decisions Shape the ESA-FIFRA Battlefield

By Steven Richardson

The near-term battlefield for Endangered Species Act-based (ESA) challenges to the U.S. Environmental Protection Agency's (EPA) pesticide regulation program has become clearer this summer. For the moment, the activist community appears to be willing to allow EPA and the ESA-implementing National Marine Fisheries and Fish & Wildlife Services some breathing room to integrate ESA consultations with the ongoing Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)[1] "registration review" evaluation of existing registered products, which is supposed to be completed by October 1, 2022.[2] Meanwhile, the activists have turned their attention to "new" products.

The existing products were the subject of the first round of litigation relating to the adequacy of EPA's ESA consideration of impacts of pesticide registration actions under FIFRA, which began over a decade ago. In those cases, plaintiffs focused on the Agency's alleged failures to consult with the Services under ESA §7 in the registration of hundreds of pesticide products.[3] The cases resulted in an injunction[4] and subsequent negotiated settlements which established deadlines for revisitation of the challenged registration determinations. More recently, however, EPA has obtained the various parties' and court's consent to adjust the established schedules to conform with the Agency's registration review plans.[5]

One reason for the plaintiffs' accommodation of EPA's plan to integrate ESA reviews into registration review was the release by EPA and the Services, in November, 2013, of an "interim approach," which committed EPA to consultation whenever there was an overlap between use of a particular pesticide and species habitat.[6] Even as EPA and the Services have made it clear that the "interim" process may be substantially revised as a result of implementation experience,[7] the activists have continued to let the process evolve. As of today, three products that had been the focus of initial litigation-driven ESA consultations regarding potential effects on salmonids—chlorpyrifos, diazinon, and malathion—have become the test cases for developing consultation procedures and principles. And the first products of that integrated effort are expected to be released by EPA later this year.[8]

More recently, however, the activists' focus has shifted. Some litigation attention still is being given to ESA concerns with existing products—in the *Ellis* case that challenges registration of two neonicotinoids[9] and the longstanding "mega" case,[10] the last of the original batch of existing product consultation-failure cases. But more attention is being given to "new" products—some new chemistries, some combinations of previously registered active ingredients. ESA-based challenges have been brought against registrations of four such products: Enlist (2,4-D and glyphosate), Acuron (the new active ingredient bicyclopyrone and atrazine, mestrione, and S-metaolachlor), cyantraniliprole, and flupyradifurone. In these cases, EPA approved the products at issue in part because they presented lower risk than existing products that would be displaced. But, the challengers allege, in none of them did EPA adequately comply with ESA consultation obligations.

The remainder of this article reviews recent decisions and pending issues as to all these cases.

Enlist: "New" Product But No Consultation Because "No Effect"

Two Court of Appeals cases challenge the registration of Dow AgroSciences' "Enlist Duo" products.[11] These herbicides combine a reduced-drift formulation of 2,4-D with glyphosate, for use on corn and soybeans. In this case, EPA undertook a full-scale ESA evaluation on a state-by-state basis. It then granted registrations in two tranches, after concluding that, because of the restrictions placed on the usage and characteristics of the chemicals, the products would have "no effect" on any threatened or endangered species or their habitat in the states in that tranche.

Although EPA's authority is well established to determine whether consultation is necessary—whether, in ESA-speak, an action "may affect" a threatened or endangered species or critical habitat[12]—the Center for Food Safety, Natural Resources Defense Counsel (NRDC), and others in October 2014 challenged EPA's approval of Dow AgroScience's Enlist Duo registration applications. Then, in February 2014, the petitioners moved to stay the registrations until the merits of the cases had been decided.

As with any stay situation, to succeed the petitioners would have had to establish (among other things) a likelihood of success on the merits and the risk of irreparable harm if relief was not granted. Faced with

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strong arguments from EPA, Dow AgroSciences (as intervenor) and CropLife America (as *amicus*) as to both issues (as well as the other pertinent issues of the balance of the equities and the public interest), the court on August 11 denied the stay motions.[13] Unfortunately, the Court issued no opinion, so it is impossible to know whether the decision reflects doubts about the petitioners' legal theories, the absence of irreparable harm—Dow AgroSciences has only introduced limited amounts of product into the market in 2015—or other considerations.

However, the process did elucidate several of the substantive issues that will be put before the Ninth Circuit. One will be the authority of EPA to apply its substantial expertise in making "may affect" determinations. In their stay briefings, petitioners took a very restrictive view of EPA's discretion. They essentially argued that the ESA requires that the test being applied by the Agency on an interim basis, as it works through the integration of FIFRA and ESA issues in the registration review process described above, must control all EPA ESA evaluations. As noted above, that test requires at least informal ESA consultation wherever there is a geographic overlap between species' presence and potential pesticide use. But the Department of Justice, representing EPA, made explicitly clear in its stay briefs a view that the highly conservative approach embodied in the "Interim Approaches" document is not compelled by statute.[14] And the Services expressly concurred in that view in a report they jointly sent to the Congress in late 2014 with EPA and the Department of Agriculture.[15]

Another key issue in the Enlist briefing will be whether EPA can grant new applications for existing products when registration review is pending. The glyphosate component of Enlist products has been a particular target in this context, by virtue of NRDC's repeated characterizations of glyphosate as a principal cause of the decline in Monarch butterfly populations. Glyphosate is far along in registration review, and successful marketing of the Enlist products will actually result in a reduction in glyphosate use. Thus, EPA has quite rationally taken the position that no independent ESA evaluation of glyphosate is necessary in the Enlist context.

Notwithstanding their effort to obtain a stay in this case, plaintiffs recently have moved to extend the merits briefing schedule. If their motion is granted, merits briefing will run through early 2016. Even if the Ninth Circuit hears argument on an accelerated basis after briefing is completed, this schedule means that no decision is likely before early summer. More realistically, a decision may be a year or more away.

Cyantraniliprole, Flupyradifurone, and Acuron (Bicyclopyrone): New Products, No Consultation

The remaining cases challenging new FIFRA registrations on ESA grounds involve the insecticides cyantraniliprole and flupyradifurone and the herbicide Acuron (which contains the new active ingredient bicyclopyrone). All were filed by the Center for Biological Diversity and mixed sets of others. In each case, EPA had determined that the products at issue were "reduced risk" products and that it was sensible to delay ESA evaluations and any resulting consultations until the processes being developed in registration review had matured.

The first case, challenging registration of cyantraniliprole, was filed in both U.S. District Court in the District of Columbia, citing the ESA as providing jurisdiction,[16] and in the U.S. Court of Appeals for the District, relying on FIFRA's judicial review provision, Section 16(b).[17] The District Court case was filed on June 3, 2014; the appellate case, four months earlier. The plaintiff's undisputed goal was to establish that District Court jurisdiction exists to review ESA compliance in the context of FIFRA registrations, and they promptly asked that the appellate case be stayed until the district court had resolved the jurisdictional issue. The Court of Appeals granted that request, and the case remains stayed pending a further court order.

The plaintiffs must have been aware that they faced an uphill battle in establishing district court jurisdiction. Requiring that the challenge be heard in the Court of Appeals is consistent with both longstanding D.C. Circuit precedent[18] and more recent Ninth Circuit rulings.[19] It came as little surprise, therefore, when on July 27, District Court Judge Gladys Kessler granted the motions of EPA and the intervening registrants to dismiss the cyantraniliprole district court case.[20] Unsurprisingly, Judge Kessler cited the D.C. Circuit rule that "[i]f a special statutory review procedure [exists], it is ordinarily supposed that Congress intended that procedure to be the exclusive means of obtaining judicial review of those cases to which it applies,[21] and a case that specifically applied that rule in the FIFRA context [22] and specifically that FIFRA contained just such a provision. She also noted the consistent recent Ninth Circuit precedent to the same effect.[23]

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Also unsurprisingly, given their request to hold the FIFRA-based parallel case in abeyance, plaintiffs quickly filed an appeal of Judge Kessler's decision, and moved to consolidate it with the FIFRA appeal. Before the appellate court could rule on that consolidation motion, however, EPA on July 27 filed a Motion for Summary Affirmance of the District Court decision. That motion is currently pending, with plaintiffs/appellants response filed on September 3 and EPA's reply expected on September 18.

Also currently pending, but being held in abeyance until resolution of the jurisdictional issue in the cyantraniliprole case, are two other review proceedings filed by the Center for Biological Diversity (CBD) and others in the D.C. Circuit, pursuant to FIFRA § 16(b). These are the cases challenging two other new active ingredients, flupyradifurone[24] and Acuron (bicyclopyrone).[25] Petitioners in the two cases have also served on EPA 90 day notice, letters necessary to establish District Court jurisdiction, should Judge Kessler's cyantraniliprole decision be overturned, but those cases are unlikely to be filed if it is affirmed.

Based on the precedent, affirmance seems far more likely than not. If so, attention in the D.C. Circuit will turn to a question not previously litigated: EPA's discretion to defer ESA evaluations on registration actions it determines do not merit priority attention. This is an issue independent of the question raised in the Enlist litigation, of course, where the Agency undertook an ESA analysis, but concluded that because the action would have no impact on species or their habitat, no consultation was required. That will place more squarely before a court fundamental question of the relationship between FIFRA and ESA than has any other case since the Ninth Circuit's ruling in *Washington Toxics Coalition v. EPA* in 2005. Those cases, therefore, will be of considerable importance.

Ellis v. Housenger: Challenges to Older Neonicotinoid Registrations

A third decision this summer that will shape forthcoming ESA litigation was the June 12 ruling by District Court Judge Maxine M. Chesney in *Ellis v. Housenger,* a case which challenges the registration and ongoing use of the neonicotinoid pesticides chlothianidin and thiamethoxam. In April 2014, Judge Chesney had dismissed a number of the original claims in which plaintiffs sought to block the use of these alleged bee-killing neonicotinoid products.[26] That order allowed several claims to survive, however. In her June decision, Judge Chesney held that review of the legality of EPA's ESA-related decisions connected with those registrations was not limited to the record.[27] This opened the door to plaintiffs' reliance on expert testimony regarding the threat to species that the registrations allegedly present, and allowed discovery by EPA and the intervening registrants into those experts' opinions.

The result is discovery and, likely, subsequent *Daubert* motions challenging the experts' qualifications.[28] This process probably will continue into the coming winter. Only after those matters are put to rest will Petitioner's motion for summary judgment on liability be heard, and cross motions from the defendants and intervenors. And the schedule for that briefing means no decision will be forthcoming before early summer: the first motion is to be filed
28 days after any Daubert motions are resolved, or (if no motions are filed) on January 29, 2016, and further briefing will continue for four months.

Mega: The Last of the Scheduling Cases?

One more case is likely to be decided in the next several months—or, at least, in 2016—that will affect the future of FIFRA-ESA integration. This is the so-called "mega" case, in which CBD originally (in 2010) challenged EPA's registration actions pertaining to product registrations related to 383 pesticide active ingredients and their effect on over 214 species. After giving the plaintiffs three opportunities to write a viable complaint, in October, 2014, District Court Magistrate Judge Joseph Spero dismissed all 31 counts in the third amended complaint that alleged consultation failures.[29] But he allowed a number of counts to survive. All of these allege EPA failed to reinitiate consultation as to products after various actions specified in the Services' ESA-implementing regulations occurred. But further action on those surviving has been deferred while plaintiffs pursue appeal of the dismissals.

The issues in the pending appeal include the same district court jurisdictional issue presented in the cyantraniliprole case, along with whether a failure-to-consult claim can be based on nothing more than EPA's continued authority over a pesticide registration. The issues have now been fully briefed, but argument has not yet been scheduled. Given Ninth Circuit calendars, it is unlikely that it will be heard before the new year. If the Ninth

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Circuit reverses Judge Spero, this case will again become alive with both failure to consult and failure to reinitiate claims. Even if the court affirms Judge Spero, however—which Circuit precedent establishes should be the case—attention will turn to the reinitiation claims unless the plaintiffs-appellants seek a further stay while seeking reconsideration or Supreme Court review.

The potential impact of those claims should not be underestimated, however. Under the Services' regulations—which Judge Spero held merit deference—every listing of a new endangered species and a variety of other developments, some as indefinite as the discovery of "new information,"[30] could trigger an obligation to reopen previously-completed consultations. If broadly interpreted, this holding could frustrate all of EPA's efforts to bring administrative regularity to the FIFRA-ESA integration process by incorporating "catch-up" reviews of existing products in registration review. And a decision addressing the issue is likely to be reached at a time EPA and the Services are trying to determine or implement the lessons learned from those three test cases.

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[1]*See* 7 U.S.C. §§ 135 *et seq.*

[2]But they continue to keep the pressure on the services. *See e.g.*, *Ctr. for Biological Diversity v. U.S. Dep't of Interior*, No. 15-CV-00658-JCS, 2015 WL 5012889 (N.D. Cal. Aug. 24, 2015).

[3]*See, e.g.*, *Washington Toxics Coal. v. EPA*, 413 F.3d 1024, 1028 (9th Cir. 2005); *Ctr. for Biological Diversity v. EPA*, 65 F. Supp. 3d 742 (N.D. Cal. 2014).

[4]*See* Order Granting Injunctive Relief, *Washington Toxics Coal. v. EPA,* No. 01-0132 (W.D. Wash. Jan. 22, 2004).

[5]Registration review is a process by which EPA reviews and updates the scientific basis for its prior conclusion that existing pesticides meet FIFRA's standard of not causing unreasonable adverse effects on the environment. FIFRA Section 3(g) requires that reviews occur every fifteen years. Prior to the initiation of the registration review program, EPA implemented a similar "reregistration" program under authority of FIFRA Section 4.

[6]Interim Approaches for National-Level Pesticide Endangered Species Act Assessments Based on the Recommendations of the National Academy of Sciences April 2013 Report (November 2013), *available at* http://www.epa.gov/espp/2013/interagency.pdf.

[7]EPA, Fish & Wildlife Serv., Nat'l Marine Fisheries Serv., and Dep't of Agric., *Interim Report to Congress on Endangered Species Act Implementation in Pesticide Evaluation Programs* at 1 (Nov. 2014), *available at* http://www.epa.gov/oppfead1/endanger/2014/esa-reporttocongress.pdf; Brief of Respondent at 16-18, *Ctr. for Food Safety v. EPA*, No. 14-73359 (9th Cir. Mar. 13, 2015).

[8]Those will be environmental assessments; the ultimate determination as to whether consultation is appropriate and the scope of any consultation will not come for months thereafter.

[9]*Ellis v. Housenger,* No. 13-1266 (N. D. Cal. filed Mar. 21, 2013).

[10]*Center for Biological Diversity v. EPA*, No. 14-16977 (9th Cir. filed Jun. 20, 2015).

[11]The cases, *Natural Resources Defense Council v. EPA* (9th Cir., Nos. 14-73353, 15-71213) and *Center for Food Safety v. EPA* (9th Cir., Nos. 14-73359, 15-71207) were consolidated.

[12]*See* 40 C.F.R. § 402.14.

[13]*See* Order, *Natural Res. Def. Council v. EPA*, No. 14-73353 (9th Cir. Aug. 11, 2015).

[14]*See* Brief of Respondent at 16-18, *Ctr. for Food Safety v. EPA*, No. 14-73359 (9th Cir. Mar. 13, 2015).

[15]*Interim Report to Congress on Endangered Species Act Implementation* at 1.

[16]*See* Complaint at 6, *Center for Food Safety v. EPA*, No. 14-cv-942 (D.D.C. June 4, 2014).

[17]*See* Petition for Review, *Ctr. for Biological Diversity v. EPA,* No. 14-1036 (D.C. Cir. Mar. 24, 2014).

[18]*Envtl. Def. Fund, Inc. v. Costle*, 631 F.2d 922, 926–32 (D.C. Cir.1980).

[19]*See, e.g.*, *United Farm Workers of Am., AFL–CIO v. Adm'r, EPA*, 592 F.3d 1080, 1082–83 (9th Cir.2010).

[20]*See Ctr for Biological Diversity v. EPA*, No. 14-942, 2015 WL 2342394, at *8 (D.D.C. May 14, 2015).

[21]*Id.* at *5 (quoting *Media Access Project v. FCC*, 883 F.2d 1063, 1067 (D.C. Cir. 1989).

[22]*Envtl. Def. Fund, Inc. v. EPA*, 485 F.2d 780, 783 (D.C.Cir.1973).

[23]*See, e.g.*, *Am. Bird Conservancy v. FCC*, 545 F.3d 1190, 1194 (9th Cir.2008); *Ctr. for Biological Diversity v. EPA*, No. 11–cv–00293, 2013 WL 1729573, at *18 (N.D. Cal. Apr. 22, 2013).

[24]*Ctr. for Biological Diversity v. EPA*, No. 15-1054 (D.C. Cir. filed Mar. 13, 2015).

[25]*Ctr. for Biological Diversity v. EPA*, No. 15-1176 (D.C. Cir. filed June 18, 2015).

[26]*Ellis v. Bradbury*, No. C–13–1266, 2014 WL 1569271 (N.D. Cal. Apr. 18, 2014).

[27]*Ellis v. Housenger*, No. C-13-1266, 2015 WL 3660079, at *4 (N.D. Cal. June 12, 2015).

[28]*See Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993)

[29]*Ctr. for Biological Diversity v. EPA*, 65 F. Supp. 3d 742, 772 (N.D. Cal. 2014).

[30]50 C.F.R. § 402.16.

Clean Power Plan Promotes Renewables

By Joseph S. Kakesh

On August 3, 2015, EPA announced its controversial, final "Clean Power Plan" regulations.[1] The regulations require states to submit plans to EPA to gradually reduce carbon dioxide (CO_2) emissions from existing fossil fuel-powered electric power plants (EGUs). Reductions are to begin in 2022 and continue through 2030. The Plan contains a number of significant changes from the proposed regulations that have far-reaching ramifications for the entire energy industry and energy users. These are described below.

Perhaps the most important changes relate to EPA's increased emphasis on renewable energy (*e.g.*, wind, solar, hydropower) to reach CO_2 emissions reductions goals. The Clean Power Plan provides the best opportunity yet for the renewable energy industry to become more integrated into our nation's electric power grid. That opportunity would come at the cost of not only the continued use of coal but also the continued expansion of the use of natural gas. Thus, we can expect significant litigation challenging most aspects of the Plan by industry stakeholders.

1. Background – Proposed Clean Power Plan

EPA issued the Clean Power Plan pursuant to Section 111(d) of the Clean Air Act. That section requires EPA to issue regulations directing the states to submit plans that "establish standards of performance for any existing source for any air pollutant."[2] A "standard of performance" is "a standard for emissions of air pollutants which reflects the degree of emission limitation achievable through the application of the best system of emission reduction [BSER] . . . [EPA] determines has been adequately demonstrated."[3]

EPA proposed to establish state-specific CO_2 emissions standards (the "standard of performance") based on what EPA determined to be BSER for CO_2 emissions for each state. Each state's standard would vary based on a number of factors, including the current mix of energy sources in the state, the useful life of existing EGUs in the state, and current trends in the state toward increasing use of renewable energy sources.

In the proposed Clean Power Plan regulations, EPA determined that the BSER would require states to consider not only reducing emissions from EGUs themselves, but also "beyond the fence line" strategies for reducing their reliance on fossil fuels.[4] These so-called BSER "building blocks" provided the basis for EPA's CO_2 emissions standard of performance in the proposed Plan.

EPA addressed four building blocks in the proposed rule: (1) reduction of fossil fuel EGU CO_2 emissions through heat rate[5] improvements; (2) substitution of generation from existing natural gas EGUs for coal–fired EGUs and establishment of substitution rates based on the "nameplate" capacity of natural gas EGUs (*i.e.*, the full capacity of the EGU when new); (3) substitution of generation by fossil fuel-powered EGUs with expanded low or zero-carbon electricity generation, including existing, under-construction, and future nuclear and renewable energy sources; and (4) application of demand-side efficiency measures to reduce amount of energy required.[6]

Several industry stakeholders sought to challenge EPA's authority to issue the Plan even before comments had been received. The U.S. Court of Appeals for the District of Columbia Circuit dismissed those suits, holding that the Proposed Plan was not final agency action subject to judicial review.[7]

2. Changes to the Clean Power Plan that Increase Emphasis on Renewable Energy

In response to millions of public comments, and in light of what it states is more accurate information regarding the current use of renewable energy and the pace of renewable energy technology development, EPA in the Final Clean Power Plan increased its final target for overall CO_2 emissions reductions nationwide from 30 to 32 percent. At the same time, however, EPA extended the initial date by which states are to meet interim CO_2 emissions reduction targets from 2020 to 2022. In doing so, EPA also significantly revised the BSER to more heavily emphasize renewable energy. The Agency also created an emissions credit incentive program to spur states to increase renewable energy capacity in 2020 and 2021.

a. Less Favorable Treatment of Natural Gas

In the final rule, EPA revised its estimate of the available capacity at existing natural gas EGUs based on what it deemed more realistic information. Rather than base its calculations on "nameplate" capacity, EPA stated that it based them on data regarding the actual operating capacity of the EGUs.[8]

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The upshot of this recalculation is that less CO_2 emissions reductions may be realized through shifting energy production from coal-fired EGUs to natural gas EGUs than EPA originally estimated. Consequently, reductions must be found elsewhere —presumably through the increased use of renewable energy.

EPA also provided a more explicit explanation of why it does not include newly-constructed natural gas EGUs (as opposed to increased capacity at existing natural gas EGUs) as a component of BSER. EPA asserted that because of the long life of such EGUs they would not, over the course of their working life, decrease overall CO_2 emissions.[9] EPA stated that "[u]nlike emission reductions achieved through the use of any of the building blocks, emission reductions achieved through the use of new [natural gas] capacity require the construction of additional CO_2-emitting generating capacity, a consequence that is inconsistent with the long-term need to continue reducing CO_2 emissions beyond the reductions that will be achieved through this rule."[10]

b. More Favorable Treatment of Renewable Energy Technology

EPA also recalculated the cost-effectiveness of existing renewable energy technology and the availability of existing renewable energy capacity. EPA stated that "[t]he final guidelines' BSER determination . . . takes into account recent reductions in the cost of clean energy technology, as well as projections of continuing cost reductions, and continuing increases in [renewable energy deployment" in carving out a larger role for renewable energy.[11]

EPA also abandoned its determination in the proposed regulations that renewable energy capacity existing at baseline (which for the Clean Power Plan is the year 2012) is a component of BSER.[12] EPA stated that such capacity does nothing to reduce CO2 emissions from baseline and thus could not be part of a best system of emissions reduction.[13] By making existing renewable energy capacity immaterial to the BSER, EPA put greater emphasis on new and expanded renewable energy capacity.

c. Incentives for Early Use of Renewable Energy

In response to concerns regarding the timing and path for implementation of the Clean Power Plan, EPA lengthened the time period by which states must meet the first interim CO_2 emission standards from 2020 to 2022.[14] To further incentivize the use of renewable energy, EPA created in the final rule the Clean Energy Incentive Program (CEIP).[15] Under the CEIP, and, depending on the type of emission standard they adopt (*e.g.*, mass-based or rate-based), states may earn emissions allowances or emission reductions credits (ERCs) in 2020 and 2021. They can do this by creating new wind and solar energy capacity or reducing electricity costs in low-income communities.[16] These credits can be banked and used in 2022 and later or else traded.

3. Litigation Has Already Begun

The final Clean Power Plan may prove to be a boon for the renewable energy industry. The Plan remains controversial with others, however, especially with respect to any requirements that go beyond measures that directly affect CO_2 emissions reductions at fossil fuel-fired EGUs themselves. Many industry stakeholders have argued that such requirements go beyond EPA's authority under Section 111 of the Clean Air Act.

Sensitive to these "beyond the fence line" challenges, EPA dropped from the final rule a proposal (Building Block 4) to include demand-side energy efficiency measures as part of BSER. But the Agency asserts that it remains confident that the other components of BSER (Building Blocks 2 and 3, which are described above) are well within its authority. Nonetheless, even though the final regulations have not yet been published in the Federal Register, West Virginia and other coal-producing states filed an emergency petition to stay them.[17] The petition was denied.[18] Much more litigation is on the horizon. Renewable energy stakeholders and advocates would be wise to be prepared to jump into the fray.

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[1]EPA, Carbon Pollution Emission Guidelines for Existing Stationary Sources: Electric Utility Generating Units, Final Rule, prepublication version ("Final Clean Power Plan") (August 3, 2015), *available at* http://www2.epa.gov/sites/production/files/2015-08/documents/cpp-final-rule.pdf.

[2]42 U.S.C. § 7411(d)(1)(A). In 2007, the Supreme Court held that CO_2 was an "air pollutant" under the Act. *See Massachusetts v. EPA*, 549 U.S. 497 (2007). *See id.* § 7411(b)(1)(A).

[3]42 U.S.C. § 7411(a)(1).

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New Restrictions on Shipping Lithium ion Batteries by Air Expected

By George A. Kerchner

Recent recommendations from aircraft manufacturers, together with concerns expressed by pilots' associations and U.S. and international regulators, have resulted in a number of significant proposals for amending the international lithium ion battery dangerous goods air transport regulations. These proposals will be addressed by the International Civil Aviation Organization (ICAO) Dangerous Goods Panel in Montreal October 19 – 30, 2015.

If proposed changes are adopted by ICAO, they will have a significant economic impact on companies that ship lithium ion batteries by air. But the changes are not expected to impact the transport of equipment containing the batteries or airline passengers with lithium ion batteries in their carry-on baggage.

The aircraft manufacturers' recommendations primarily address the risks associated with "high density" or "bulk shipments" in cargo holds on passenger and cargo-only aircraft. As a result of these recommendations, numerous airlines have adopted new restrictions on transporting lithium ion batteries. These restrictions already are having an impact on how companies transport their lithium ion batteries globally.

The proposals that will be considered by ICAO next month could further complicate supply chain management.

For example, the International Federation of Airline Pilots Association (IFALPA) is seeking a ban on the transport of lithium ion batteries as cargo on passenger aircraft. Because many parts of the world are not served by cargo-only aircraft, this will further disrupt supply chains if IFALPA's proposal is adopted by ICAO.

Any changes adopted by the ICAO Dangerous Goods Panel during their October meeting will not go into effect until January 1, 2017.

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[4]*See* EPA, Carbon Pollution Emission Guidelines for Existing Stationary Sources: Electric Utility Generating Units, Proposed Rule ("Proposed Clean Power Plan"), 79 Fed. Reg. 34,830, 34,852 (June 18, 2014).

[5]"Heat rate improvements are changes implemented at an EGU that increase the efficiency with which the EGU converts fuel energy to electric energy, thereby reducing the amount of fuel needed to produce the same amount of electricity and consequently lowering the amount of CO2 produced as a byproduct of fuel combustion." Final Clean Power Plan at 647.

[6]Proposed Clean Power Plan, 79 Fed. Reg. at 34,858.

[7]*See In re Murray Energy Corp.*, 783 F.3d 330 (D.C. Cir. 2015).

[8]Final Clean Power Plan at 341.

[9]*Id.* at 346.

[10]*Id.*

[11]*Id.* at 65.

[12]"As part of the adjustment in approach, we have also refocused quantification solely on generation from new RE generating capacity rather than total (new and existing) RE generating capacity as in the proposal." Final Clean Power Plan at 343.

[13]*See id.*

[14]*Id.* at 60-61.

[15]*See id.* at 864-879.

[16]*See id.* at 74, 868.

[17]*See, e.g.*, *In re West Virginia, et al.*, Case No. 15-1277 (D.C. Cir. Aug. 13, 2015) (emergency petition for extraordinary writ of stay filed by West Virginia and other states to stay implementation of the final Clean Power Plan regulations).

[18]*See id. per curiam order* (D.C. Cir. Sept. 9, 2015).

regulation and that a more limited regulation would not be equally effective.[5]

This question was addressed by the *en banc* D.C. Circuit in *American Meat*. The court applied the *Zauderer* framework, even though there was nothing misleading about the meat labels absent the disclosure.[6] It found that the purpose of protecting commercial speech under the First Amendment was to provide consumer access to information. Because disclosures—unlike restrictions—provided additional information, the court found companies' interest in nondisclosure minimal, as long as the disclosure was factual and noncontroversial.[7] But by applying less demanding scrutiny in these new circumstances, the D.C. Circuit in effect narrowed companies' First Amendment rights and invited additional mandates.

Overturning SEC's Conflict Mineral Rule

The debate continued in litigation over a Securities and Exchange Commission (SEC) regulation, required in the Dodd-Frank Act, that required companies sourcing minerals from the Democratic Republic of the Congo to disclose on websites that products were not "conflict free."[8] On August 18, revisiting an earlier decision with the benefit of the *American Meat* case, a panel majority in *National Association of Manufacturers v. Securities and Exchange Commission* overturned the rule, finding in favor of the corporate speakers.[9]

The court found two reasons to reject the conflict-mineral rule. First, the information was not on advertisements (as in *Zauderer*) or at a product's point of sale (as in *American Meat*). Instead, the SEC rule required website and financial disclosures, and the panel majority found a stricter standard of review should apply. And under that standard, the SEC disclosure infringed on companies' free speech rights.[10]

This rationale—that a company seems to have weaker First Amendment interests when speech is more closely tethered to product sales—could prove important in future litigation. After this case, commercial speech far removed from the point of sale could receive more protection than the same speech in product advertisements.

Second, the court found that the required disclosure was controversial, and thus would fail even *Zauderer*'s lowest standard of review.[11] The court identified controversy about whether the conflict-mineral disclosure would improve humanitarian conditions in the Congo. Indeed, some critics contended the rule would worsen the crisis. According to the court, the evidence in support of the rule was too speculative. Equally troubling, the disclosure placed a scarlet letter around the neck of companies by "convey[ing] moral responsibility for the Congo war."[12]

Judge Srinivasan wrote an opinion dissenting from both conclusions. He criticized the majority for ignoring the full court's decision in *American Meat*, under which he would have applied *Zauderer*'s lower standard of review and found that the "conflict free" disclosure was no more objectionable than run-of-the-mill factual and noncontroversial disclosures routinely required by other laws.[13] But even if the more demanding standard applied, the dissent still thought the rule passed scrutiny.[14]

What Now?

The two recent D.C. Circuit opinions reconfigure battle lines in a circuit split on whether the government can compel disclosures on non-misleading commercial speech. For example, while the Third and Tenth Circuits appear to restrict the lowest standard of review to misleading advertisements, the D.C. Circuit has now joined the First and Second Circuits in applying the lower standard to even non-misleading advertisements.

For its part, the Supreme Court has never applied *Zauderer* outside the context of misleading advertisements, despite opportunities to do so. But its few decisions leave lower courts little "guidance on the permissibility and scope" of disclosures when speech is not misleading.[15]

The *National Association of Manufacturers* opinion also presents a second potential battle line. Supreme Court cases since *Zauderer* have declined to apply it beyond disclosures on voluntary advertisements. For instance, the Supreme Court has found that a company cannot be compelled to pay for an industry-wide advertisement to which it objects.[16] But *American Meat* addressed disclaimers on product labels and not voluntary advertisements. Arguably, therefore, it conflicts with these cases and is outside the narrow *advertising* exception of *Zauderer*.

This conflict already is being revisited in a challenge to a Vermont regulation requiring disclosure on labels of genetically modified ingredients.[17] And the SEC has been ordered to expedite a rule requiring oil and gas companies to disclose payments to foreign governments that likely will raise similar

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First Amendment issues.[18] Compelled disclosures in non-advertising contexts will require courts to consider whether the D.C. Circuit is correct that the constitutionality of a disclosure requirement depends in part on its connection to a sale or advertisement.

Until the Supreme Court offers further guidance, both of these issues likely will continue to differ across three-judge panels and regions. The *National Association of Manufacturers* case may present the first opportunity for clarification. The parties have until early October to determine whether to seek rehearing by the full court in the D.C. Circuit, and even longer to decide whether to appeal to the Supreme Court. In the meantime, product companies will continue to face burgeoning government mandates and informational obligations.

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[1] *Am. Meat Inst. v. U.S. Dep't of Agric.*, 760 F.3d 18, 27 (D.C. Cir. 2014) (*en banc*).

[2] *Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio*, 471 U.S. 626 (1985).

[3] *See Hurley v. Irish-Am. Gay, Lesbian & Bisexual Grp. of Boston*, 515 U.S. 557, 574 (1977).

[4] *Id.* at 651.

[5] *See, e.g.*, *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of New York*, 447 U.S. 557, 564 (1980).

[6] *American Meat*, 760 F.3d at 22-23.

[7] *Id.* at 26.

[8] For further background, see *Nat'l Ass'n of Mfrs. v. SEC*, 748 F.3d 359 (D.C. Cir. 2014).

[9] *Nat'l Ass'n of Mfrs. v. SEC*, No. 13-5252, 2015 WL 5089667 (D.C. Cir. Aug. 18, 2015).

[10] *Id.* at *3.

[11] *Id.* at *4-5.

[12] *Id.* at *7.

[13] *Id.* at *14, 16, 18.

[14] *Id.* at *19-20.

[15] *Borgner v. Fla. Bd. of Dentistry*, 537 U.S. 1080 (2002) (Thomas, J., dissenting from denial of certiorari).

[16] *See United States v. United Foods, Inc.*, 533 U.S. 405 (2001); *Hurley v. Irish-American Gay, Lesbian and Bisexual Group of Boston*, 515 U.S. 557 (1995).

[17] *See Grocery Mfrs. Ass'n v. Sorrell*, No. 5:14-cv-117, 2015 WL 1931142 (D. Vt. Apr. 27, 2015).

[18] *See Oxfam America, Inc. v. SEC*, No. 14-13648 (D. Mass. Sept. 2, 2015).

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