

The FDA's Continuing Incapacity on Livestock Antibiotics

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The Food and Drug Administration (FDA) recently recommitted itself to its policy of addressing the profligate use of antibiotics in livestock by enlisting the voluntary participation of the drug companies that make the antibiotics. Two documents issued in December 2013 reveal the details of the Agency's current plans. The first is a final guidance document describing the FDA's process for handling drug sponsors' voluntary efforts to phase out certain uses of antibiotics in animal feed and water and to bring the remaining uses under the oversight of a veterinarian. The second is a draft rule relaxing the requirements for veterinarians in exercising this oversight. This article provides the first in-depth analysis of the several different strands of the FDA's most recent announcements.

Together, the documents just issued by the FDA guarantee little more than continued delay in tackling a public health risk that has bedeviled the Agency for decades. The FDA's decision to rely on voluntary action by drug companies and to continue to allow routine uses of antibiotics in whole herds and flocks of animals in order to prevent infections brought on by stressful conditions leave potentially gaping holes in the protection the Agency purports to provide. The Agency's meager backup plans in case this endeavor does not work out as it hopes do little to comfort the skeptical. Moreover, the FDA's proposal to weaken rules for veterinary oversight undermines the Agency's plan to place veterinarians at the front line of preventing

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agricultural overuse of antibiotics. In addition, after a small outburst of transparency at the very start of the process, this whole undertaking will move underground for several years while the FDA works things out privately with participating drug companies.

Rather than pursuing this inadequate course, the FDA should do what a federal district court has already ordered it to do: complete regulatory proceedings to withdraw approvals for the mass administration of medically important antibiotics to food-producing animals. The FDA's refusal to do so rests on the mistaken legal premise that such withdrawals must be preceded by formal, trial-type hearings; this premise ignores decades of developments in administrative law and misreads the Agency's own enabling statute.

I. INTRODUCTION	326
II. WHAT HAS THE FDA JUST DONE?.....	329
III. WHAT IS WRONG WITH THE FDA'S APPROACH?.....	332
A. Depending on the Kindness of Profit Maximizers.....	333
B. From Production to Prevention.....	337
C. Veterinary Oversight.....	343
D. Keeping the Public in the Dark.....	346
IV. RECOMMENDATIONS FOR IMPROVEMENT	348
V. CONCLUSION.....	349

I. INTRODUCTION

The FDA recently recommitted itself to its policy of addressing the profligate use of antibiotics in livestock by enlisting the voluntary participation of the drug companies that make the antibiotics. Two documents issued in December 2013 reveal the details of the Agency's current plans. The first is a final guidance document describing the FDA's process for handling drug sponsors' voluntary efforts to phase out certain uses of antibiotics in animal feed and water and bring the remaining uses under the oversight of a veterinarian.¹ The second is a draft rule relaxing the requirements

1. FDA, GUIDANCE FOR INDUSTRY #213, NEW ANIMAL DRUGS AND NEW ANIMAL DRUG COMBINATION PRODUCTS ADMINISTERED IN OR ON MEDICATED FEED OR DRINKING WATER OF FOOD-PRODUCING ANIMALS: RECOMMENDATIONS FOR DRUG SPONSORS FOR VOLUNTARILY ALIGNING PRODUCT

for veterinarians in exercising this oversight.² Together, the documents portend little more than continued delay in tackling a public health risk that has bedeviled the Agency for decades.

For some sixty years, drug companies and agricultural operations have added antibiotics to the food and water of food-producing animals, not to treat active infections, but to promote the animals' growth and to prevent infections in animals kept in the stressful conditions of modern industrial agriculture.³ For fifty of these years, scientists have warned that this practice can lead to the development of antibiotic-resistant strains of bacteria and that this resistance can spread to humans.⁴ The evidence has only grown in the decades since scientists first posited this connection, reaching full expression this past fall in a report by the Centers for Disease Control and Prevention concluding that 23,000 Americans die each year due to antibiotic-resistant infections and placing part of the blame on the routine use of antibiotics in food-producing animals.⁵

For over four decades, the FDA has been mulling the risk posed by the use of antibiotics in food animals.⁶ In 1973, faced with emerging evidence of the link between antibiotic resistance in humans and the administration of tetracyclines and penicillin to food animals for the purposes of growth promotion and disease prevention, the FDA directed the makers of the relevant antibiotics to present the Agency with evidence that this practice did not pose a risk to human health.⁷ In 1977, the Agency proposed withdrawing its approval of penicillin and two forms of tetracycline for purposes of growth promotion and disease prevention on account of the risk to human health from the encouragement of antibiotic resistant

USE CONDITIONS WITH GFI #209 (Dec. 2013), *available at* <http://tinyurl.com/7cx4q72> [hereinafter GUIDANCE FOR INDUSTRY #213].

2. Veterinary Feed Directive, 78 Fed. Reg. 75,515 (proposed Dec. 12, 2013) (to be codified at 21 C.F.R. pts. 514, 558).

3. Tetracycline (Chlortetracycline and Oxytetracycline)-Containing Premixes, 42 Fed. Reg. 56,264, 56,265 (Oct. 21, 1977).

4. *Id.* at 56,266.

5. U.S. DEP'T OF HEALTH & HUM. SERVS., CTRS. FOR DISEASE CONTROL & PREVENTION, ANTIBIOTIC RESISTANCE THREATS IN THE UNITED STATES (2013), *available at* <http://tinyurl.com/k6qnonu>.

6. Lisa Heinzerling, *Undue Process at the FDA: Antibiotics, Animal Feed, and Agency Intransigence*, 37 VT. L. REV. 1007, 1010-12 (2013).

7. Antibiotics and Sulfonamide Drugs in the Feed of Animals, 38 Fed. Reg. 9811, 9813 (codified at former 21 C.F.R. § 135.109; renumbered at 21 C.F.R. § 558.15).

strains of bacteria.⁸ The Agency also announced its intention to hold hearings on the matter.⁹ (These dates are not typos: the FDA has been at this for a very, very long time.)

The FDA has never held the hearings it promised in 1977. Instead, the agency flatly announced in 2011 that it actually did not intend to hold such hearings because (wait for it)—they would *take too long*.¹⁰ In the place of regulatory proceedings to withdraw approvals for uses of antibiotics that the scientific community has concluded pose substantial risks for human health, the FDA promised a plan to work cooperatively with drug sponsors to phase out some of the risky uses of antibiotics in animal feed and to encourage veterinary oversight of the remaining uses.¹¹ In 2012, a federal district court found that such voluntary measures were no substitute for regulatory action,¹² and ordered the FDA to begin proceedings to withdraw approvals for the drugs in question.¹³ The district court's decision is now on appeal in the Second Circuit.¹⁴

In the meantime, the FDA has continued to press ahead with its thousand-points-of-light strategy for tackling the problem of antibiotic resistance brought on by routine use of antibiotics in animal agriculture. The two documents issued by the FDA in December 2013 describe the Agency's current thinking. The final guidance document tells drug companies the process for withdrawing "production uses" of their products and bringing the remaining uses under veterinary oversight; the second relaxes the requirements for veterinary oversight. Production uses are aimed at promoting growth and improving feed efficiency, not at treating active infections. The FDA will continue to allow mass medication of whole herds and flocks of livestock for purposes of preventing

8. Tetracycline (Chlortetracycline and Oxytetracycline)-Containing Premixes, 42 Fed. Reg. at 56,265. The notices pertained to penicillin and tetracyclines because the FDA's prior study of the human health risks posed by administering antibiotics to livestock had focused on penicillin and tetracyclines. *NRDC v. FDA*, 884 F. Supp. 2d 127, 132-34 (S.D.N.Y. 2012).

9. Tetracycline (Chlortetracycline and Oxytetracycline)-Containing Premixes, 42 Fed. Reg. at 56,265.

10. Withdrawal of Notices of Opportunity for a Hearing; Penicillin and Tetracycline Used in Animal Feed, 76 Fed. Reg. 246 n.8 (Dec. 22, 2011).

11. FDA, GUIDANCE FOR INDUSTRY #209, THE JUDICIOUS USE OF MEDICALLY IMPORTANT ANTIMICROBIAL DRUGS IN FOOD-PRODUCING ANIMALS 17 (2012), available at <http://tinyurl.com/ofl4ovb> [hereinafter GUIDANCE FOR INDUSTRY #209].

12. *NRDC v. FDA*, 872 F. Supp. 2d 318, 340-42 (S.D.N.Y. 2012).

13. *Id.* at 342; *NRDC v. FDA*, 884 F. Supp. 2d 108, 117-27 (S.D.N.Y. 2012).

14. Heinzerling, *supra* note 6, at 1008.

infection.

The FDA's recent initiatives are the most significant steps the FDA has taken to date to address the problem of the profligate use of antibiotics in food animals. We should all hope they succeed. As I explain here, however, the initiatives leave much to be desired, for four basic reasons. First, the success of the FDA's policy on "judicious use" depends on multiple layers of voluntary action by profit-maximizing drug companies. Although early indications of drug companies' cooperation are promising, the FDA has offered only meager backup plans in case the companies ultimately balk at the FDA's approach. Second, the FDA will continue to allow livestock producers to feed antibiotics to whole herds and flocks of animals even in the absence of active infection, in order to prevent the infections brought on by the stressful conditions of industrial agriculture. The lack of strong safeguards against overuse of antibiotics for disease prevention threatens to offset gains achieved by removing uses of antibiotics for growth promotion. Third, the FDA's proposal to weaken rules for veterinary oversight undermines the Agency's plan to place veterinarians at the front line of preventing agricultural overuse of antibiotics. Finally, as I will explain, after a small outburst of transparency at the very start of the process, this whole undertaking will move underground for three years while the FDA works things out privately with participating drug companies.

While other commentators have offered excellent initial critiques of the FDA's recent announcements,¹⁵ this essay provides the first in-depth analysis of the several different strands of the FDA's plan. But first, I provide more details on the recent announcements from the FDA.

II. WHAT HAS THE FDA JUST DONE?

On December 12, 2013, the FDA issued two documents that purport to address the profligate use of antibiotics in food animals. These documents flesh out the FDA's previously announced policy of "judicious use" of antibiotics in animal feed and water, a two-pronged policy that entails voluntary withdrawals of some uses of antibiotics in animal feed and veterinary oversight of the remaining

15. For a particularly lucid analysis, see Mark Bittman, *The FDA's Not-Really-Such-Good-News*, N.Y. TIMES (Dec. 17, 2013), <http://tinyurl.com/oxhts7p>.

uses.¹⁶

The first document, a final version of the Agency's Guidance for Industry #213, explains how drug sponsors can go about voluntarily phasing out certain uses of certain antibiotics in animal feed and water and phasing in veterinary oversight. The FDA is encouraging the makers of certain, named antibiotics—what it deems “medically important” antibiotics¹⁷—to voluntarily withdraw “production uses” of these antibiotics and to require the participation of a veterinarian in administering the drugs for the remaining uses.¹⁸ Production uses are those aimed at purposes such as promoting animal growth and improving feed efficiency.¹⁹

Crucially, drug makers may not abandon the approved indications for use of their products by simply doing nothing. Because the federally mandated and FDA-approved labels for drug products must include the indications for use of such products and because the FDA must approve any changes to approved drug product labels, makers of antibiotics who wish to phase out production uses of their products must formally ask the FDA to approve new labels omitting reference to production uses.²⁰ The mechanism for asking for this approval is a supplemental new animal drug application (NADA).²¹ As the FDA explains in Guidance #213, drug sponsors need not submit new information on safety or effectiveness in submitting the supplemental NADAs relating to antibiotics administered through animal feed or water, but they must submit the new labels they propose to use for these products.²² These labels will, presumably, make clear that production uses have been withdrawn. FDA does not, in Guidance #213, provide instructions on what an approvable label for this purpose might look like.

At the same time, the FDA reaffirms that it is not asking drug

16. GUIDANCE FOR INDUSTRY #209, *supra* note 11.

17. The FDA classifies antibiotics used for livestock as “medically important” based on their “human medical importance,” and includes in this category all seven of the specific drug classes that it previously—in public processes associated with Guidance # 152 on antimicrobial new animal drugs—“determined to be important for treating bacterial infections in people.” FDA, *supra* note 1, at 5.

18. *Id.* at 4-5.

19. *Id.* at 4.

20. *Id.* at 6, 8.

21. *Id.* at 10.

22. *Id.*

makers to withdraw the use of antibiotics in the feed and water of food-producing animals for purposes of disease “prevention.”²³ Prevention uses entail relatively low doses of antibiotics administered to whole herds and flocks of animals in the absence of an active infection; often, these doses are in the same range as the doses for production uses.²⁴ In Guidance #213, the FDA describes what it views as “judicious” prevention uses. The FDA expects that veterinarians will approve the use of medically important antibiotics for “prevention purposes” only to “prevent disease based on specific, known risk.”²⁵ The Agency goes on to provide a long list of considerations relevant to determining whether such a risk is present, including the mode of action of the relevant drug, the distribution of the drug in specific animal tissues, the connection to a specific agent of disease, environmental factors (such as inadequate ventilation), “host factors” (such as age, nutrition, and immune status), and “other factors (such as stress of animal transport).”²⁶ As we will see, the factors the FDA cites give veterinarians extremely broad discretion in administering antibiotics to food animals for prevention uses.

In addition to asking drug sponsors to request changes in labeling on the indications for use, the FDA is also asking drug sponsors to request changes in labeling relating to the over-the-counter (OTC) status of the relevant drugs.²⁷ The “medically important” antibiotics that are the subject of the FDA’s guidance are now offered over-the-counter (meaning that the antibiotics can be administered without the intermediation of a licensed professional), and this status is reflected on their labels. Here, too, the FDA must approve any change in this status and in the labels reflecting that status. Drug makers wishing to accede to the Agency’s request that use of their drug products in animal feed be attended by veterinary oversight must formally ask the FDA to approve a change in status

23. *Id.* at 4, 7.

24. Letter from Avinash Kar, Staff Attorney, NRDC, to the Honorable Dr. Margaret A. Hamburg, Commissioner and Dr. William T. Flynn, FDA 3 (July 12, 2012), *available at* <http://tinyurl.com/ppn8cbq> [hereinafter NRDC Comments Letter] (submitting Comments on Antibiotics in Livestock Guidance Package, Docket Nos. FDA-2011-D-0889, FDA-2010-D-0094, FDA-2010-N-0155 (Draft Guidance 213, Guidance 209, and Veterinary Feed Directive Draft)).

25. GUIDANCE FOR INDUSTRY #213, *supra* note 1, at 7.

26. *Id.*

27. *Id.*

from over-the-counter availability to one requiring a “veterinary feed directive” before administration of the drugs to animals.²⁸ A drug subject to a veterinary feed directive may be administered only with veterinary oversight, but without other requirements associated with prescription-only drugs. For antibiotics administered through animals’ water, the FDA is asking makers to switch from OTC status to prescription-only status,²⁹ as drugs administered through drinking water are, by law, not subject to veterinary feed directives.

The second document published in December 2013 is a proposed rule relaxing the requirements for such veterinary feed directives.³⁰ Of particular note is the FDA’s proposal to eliminate the federal framework for the “veterinarian-client-patient relationship” (VCPR) and to replace it with reliance on state-by-state veterinary licensing and practice requirements.³¹ In concrete terms, this means that veterinarians would be able to issue veterinary feed directives without seeing or examining the actual animals subject to the directives.³² Relatedly, the proposed rule also conspicuously provides that “oversight” of animals subject to veterinary feed directives is sufficient; previously, the FDA had required veterinary “supervision” of such animals.³³ In addition, the proposed rule trims requirements for reporting and record keeping by veterinarians and their clients.³⁴

It would be excellent if these plans for achieving the “judicious use” of antibiotics in animal agriculture worked. But, for reasons I next discuss, I am not terribly optimistic.

III. WHAT IS WRONG WITH THE FDA’S APPROACH?

The FDA’s plan has several fundamental problems. First, the

28. *Id.* at 9.

29. *Id.*

30. Veterinary Feed Directive, 78 Fed. Reg. 75,515 (proposed Dec. 12, 2013) (to be codified at 21 C.F.R. pts. 514, 558).

31. *Id.* at 75,516, 75,518-19.

32. *Cf.* 21 C.F.R. § 530.3(i) (2013) (citing the current regulation on veterinarian-client-patient relationship). This rule, which requires that a veterinarian “has recently seen and is personally acquainted with the keeping and care of the animal(s) by virtue of examination of the animal(s), and/or by medically appropriate and timely visits to the premises where the animal(s) are kept” would be undone by the FDA in its proposed rule. *Id.*

33. Veterinary Feed Directive, 78 Fed. Reg. at 75,518.

34. *Id.* at 75,520.

FDA's project may be doomed from the start on account of its dependence on voluntary actions by drug companies accustomed to reaping profits from production uses they are being asked to forgo. Second, even if they go along in ceasing production uses, agricultural operations might simply shift their rationale for adding low doses of antibiotics to the feed and water of animals from production purposes to disease prevention purposes. The Agency's criteria for continued prevention uses are so broad that it is easy to imagine prevention uses simply taking up where production uses left off. Third, veterinary oversight of production uses could help in theory, but the FDA's proposal to weaken this oversight gives cold comfort. And fourth, the secrecy that will pervade the program will keep the public from knowing whether the program has gone off the rails until some years from now.

A. Depending on the Kindness of Profit Maximizers

The first potential problem with the FDA's approach is that it depends on the voluntary efforts of drug makers to eliminate uses of their products that have likely turned a hefty profit for them. Some eighty percent of the antibiotics used in this country are used in food animals.³⁵ The FDA is asking—just asking, not requiring—drug makers to give up a share of this market. And the FDA has, in internal documents, acknowledged that “all”—*all*—of the relevant drug companies must participate in the plan in order for it to work.³⁶ One can see why this is so: even if a large number of companies agree to the FDA's plan, others could simply step into the market niche thus opened for them and defeat the purpose of the plan.

The possibility of this bad outcome appears even greater when one realizes that the FDA's plan involves not just one, but three, different layers of voluntary activity. First, the sponsors of non-generic (“pioneer” or “reference”) drugs must ask the FDA to withdraw production uses from their labels and to provide for veterinary oversight.³⁷ Then, the drug companies that market the

35. Heinzerling, *supra* note 6, at 1010.

36. See FDA, PRIVILEGED AND CONFIDENTIAL (2012), available at <http://tinyurl.com/qxls9kq> (“[T]he voluntary approach will only work if all sponsors decide it is in their best interest to work cooperatively with the agency.”).

37. GUIDANCE FOR INDUSTRY #213, *supra* note 1, at 15.

generic versions of these drugs must do the same.³⁸ Finally, the companies that market combination drugs that incorporate one or more of the relevant antibiotics must also come on board with the voluntary program.³⁹

Happily, and perhaps surprisingly, it appears that, so far, drug sponsors are responding positively to the FDA's call for voluntary action. Of the twenty-six drug companies the FDA has identified as the sponsors of medically important animal antibiotics, twenty-five have, according to the FDA, "agreed in writing that they intend to engage in the judicious use strategy by seeking withdrawal of approvals relating to any production uses and changing the marketing status of their products from over-the-counter to use by Veterinary Feed Directive or prescription."⁴⁰ The FDA has reported that, in 2011, these twenty-five companies represented 99.95% of the total sales of the antibiotics addressed by the judicious use policy.⁴¹ Moreover, the FDA reports, the twenty-six companies that sponsor medically important animal antibiotics include not only the sponsors of pioneer drugs, but also the sponsors of generic and combination drugs.⁴² The one company that did not agree to participate in the FDA's voluntary plan, Pharmaq AS, apparently makes a drug used only in fish.⁴³

This is all good news. But it is probably too soon to crack open the champagne. The FDA has reported that twenty-five drug sponsors have "agreed to engage with FDA as defined in Guidance #213."⁴⁴ The drug sponsors and the FDA still need to complete the process of withdrawing production uses for these antibiotics and moving to Veterinary Feed Directive or prescription status. It remains to be seen whether the drug sponsors will request any other changes in their labeling that might pertain to the human health risk posed by the administration of antibiotics to food animals. It also remains to be seen whether the drug sponsors intend to change the labeling and OTC status of all of the drugs the

38. *Id.*

39. *Id.* at 16.

40. FDA, UPDATE ON ANIMAL PHARMACEUTICAL INDUSTRY RESPONSE TO GUIDANCE #213 (2014) available at <http://tinyurl.com/ncdgzsk>.

41. *Id.*

42. *Id.*

43. P.J. Huffstutter, *U.S. Drug Firms Move to Bar Antibiotic Use in Livestock Growth*, REUTERS (Mar. 27, 2014, 8:58 PM), <http://tinyurl.com/pnjrt9u>.

44. FDA, *supra* note 40.

FDA has deemed “medically important”; if the drug sponsors disagree with the FDA about the medical importance of some of their drug products, they may balk at changing the labeling and OTC status of those specific drugs. Indeed, Phibro Animal Health, a leading manufacturer of medicated animal feeds, has stated its intention to seek reclassification of one of its antibiotics as not “medically important.”⁴⁵

If the drug sponsors and the FDA have any falling out during this process, the FDA has only the slimmest backup plan. This is especially true for generic and combination drugs. With respect to generics, the FDA has said that it “expect[s]” generic sponsors to respond to any changes in labeling for their reference drugs, and to submit supplemental NADAs to change their own labeling.⁴⁶ If generic sponsors do not do so, the FDA warns that they face the possibility of suspension of the approval of their drugs.⁴⁷ Here, the Agency cites a statutory provision that does not refer to labeling but instead allows the FDA to withdraw or suspend approval of a generic product if the Agency finds that the reference drug was withdrawn for reasons of safety or effectiveness.⁴⁸ However, the FDA’s decades-long refusal to make *any* finding on safety with respect to production uses of antibiotics in food animals bodes ill for the Agency’s use of this statutory provision.⁴⁹ Moreover, in the same discussion, the Agency cites its regulation on the process for suspending generic approvals⁵⁰—a process that threatens the same kind of prolonged proceedings the Agency is trying mightily to avoid by relying on voluntary actions by drug sponsors. Note, too, that in a different context, the FDA has just proposed to revise its longstanding policy that generic labels must be identical to reference labels even past the initial approval period.⁵¹ In these ways, the FDA’s warning to generic drug sponsors about the

45. Richard Coulter & Larry Miller, *The Future of Stafac® (Virginiamycin) for Veterinary Use*, PHIBRO ANIMAL HEALTH CORP. (Apr. 12, 2013), available at <http://tinyurl.com/lpszaxu>.

46. GUIDANCE FOR INDUSTRY #213, *supra* note 1, at 15.

47. *Id.*

48. 21 U.S.C. § 360(b)(2)(G) (2012).

49. On the Agency’s long-running intransigence on this issue, see Heinzerling, *supra* note 6.

50. 21 C.F.R. § 314.153(b) (2013).

51. Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products, 78 Fed. Reg. 67,985, 67,994 (proposed Nov. 13, 2013) (to be codified at 21 C.F.R. pts. 314, 601).

consequences of inaction following a labeling change for reference drugs is quite hollow.

The FDA's discussion of its expectations for makers of combination drugs incorporating antibiotics that have been withdrawn from production uses and placed under the oversight of veterinarians is even less encouraging. Here, the Agency simply states that it "expects" such sponsors to "voluntarily" follow suit if the sponsor of any drug included in the combination drug withdraws production use from its labeling.⁵² If makers of combination drugs do not do so, the FDA "intends to consider further action as warranted in accordance with existing provisions of the FD&C Act for addressing matters related to the safety of approved combination new animal drugs."⁵³ Unlike with generic drugs, the FDA cites no specific statutory provision buttressing this threat. Here, it is likely that the FDA will be left in the same position that has paralyzed it for decades—unable to take action against recalcitrant drug sponsors unless it is willing to do the work to find that their products are not safe and withdraw their approvals. In announcing an intent "to consider further action" in these circumstances, the FDA is whistling in the dark.

The FDA also appears to concede that it has few good options for dealing with combination-drug sponsors that fail to switch their products from OTC to a status requiring veterinary feed directives, once the sponsor of a drug contained in their products does so. Once again, the Agency says that it "expects" the combination-drug sponsors to follow along, but here the Agency adds an argument that the combination-drug sponsors are "essentially compelled" by law to make this change once a sponsor of one of their component drugs does so.⁵⁴ The Agency's language is so carefully hedged—"essentially compelled," "in effect, "should generally"—that it sounds like the Agency is trying to convince even itself that it has real recourse against combination-drug sponsors that choose not to toe the line.

The FDA's reliance on voluntary efforts becomes even more unsettling when one considers the magnitude of the charitable corporate action required if the FDA's program is to succeed. As I have noted, FDA has said in internal documents that it needs "all" of

52. GUIDANCE FOR INDUSTRY #213, *supra* note 1, at 16.

53. *Id.*

54. *Id.* at 17.

the relevant drug sponsors to participate if its program is to work.⁵⁵ What happens if, despite their initial apparent embrace of the FDA's program, drug sponsors come to see the FDA's program as a market opportunity rather than a call to serve?

Once again, the FDA's backup plan is less than reassuring: if after a three-year phase in the Agency determines "that adequate progress has not been made," the Agency "will consider whether further action under the existing provisions of the FD&C Act may be appropriate."⁵⁶ The FDA does not cite the provisions it has in mind, but certainly they would include the very provisions the Agency has disparaged in the course of opting for voluntary over regulatory action. As the magistrate judge in the district court put it in his decision rejecting the FDA's refusal to take action on agricultural uses of antibiotics:

In effect, the FDA is refusing to follow the statutory mandate of withdrawal proceedings on the ground that such proceedings are not effective because they take too long.⁵⁷ . . . One can only wonder what conceding the absence of an effective regulatory mechanism signals to the industry which the FDA is obligated to regulate.⁵⁸

One can only wonder indeed. After spending years arguing that regulatory proceedings on agricultural antibiotics are well nigh impossible, the FDA can hardly now expect to scare any drug sponsor into action by threatening such proceedings.

B. From Production to Prevention

Perhaps the most serious problem with the FDA's approach is that the Agency will continue to allow livestock producers to administer antibiotics to whole herds and flocks of animals through their feed and water, for the purpose of preventing rather than treating infections. The concern is that profligate use of antibiotics may continue virtually unabated, but under the banner of disease prevention instead of growth promotion.

The long-running debate over antibiotics used in animal agriculture has focused overwhelmingly on "mass medication" of

55. See FDA, *supra* note 36, and accompanying text.

56. GUIDANCE FOR INDUSTRY #213, *supra* note 1, at 9.

57. NRDC v. FDA, 872 F. Supp. 2d 318, 339 (S.D.N.Y. 2012).

58. *Id.* at 339 n.23.

food animals—the administration of relatively low doses of antibiotics to whole herds and flocks of animals in the absence of an active infection in individual animals.⁵⁹ The doses in such cases are often referred to as “subtherapeutic” because they are lower than the doses used to treat active infections in specific animals, or even “nontherapeutic” because they are often used for nonmedical purposes. As Stuart Levy, a prominent researcher in the field, has put it, “long-term exposure to low doses is the perfect formula for selecting increasing numbers of resistant bacteria in the treated animals.”⁶⁰ Low doses permit the survival of antibiotic-resistant strains of bacteria that would have been killed at higher doses.⁶¹

For this reason, for a long time the FDA considered together all agricultural uses that entail administering relatively low doses of antibiotics to whole herds and flocks of animals in the absence of an active infection. In 1973, for example, when the Agency first expressed its concerns that such uses of antibiotics posed risks to human health, the Agency did not distinguish between production uses (growth promotion and feed efficiency) and prevention uses; it considered both to be worrisome from the perspective of antibiotic resistance.⁶² Likewise, in 1977, when the Agency proposed to withdraw approvals for use of tetracycline and penicillin in animal feed, it addressed production and prevention uses alike.⁶³ More recently, in its Guidance #152 issued in 2003, addressing safety evaluations of new, antimicrobial animal drugs, the FDA indicated that the use of such drugs in whole herds or flocks of animals for extended periods of time was an important factor in determining the riskiness of the new drug; it did not suggest a distinction between production and prevention uses in evaluating riskiness.⁶⁴

59. See, e.g., Scott A. McEwen & Paula J. Fedorka-Cray, *Antimicrobial Use and Resistance in Animals*, 34 CLINICAL INFECTIOUS DISEASES S93, S93-S94 (2002) (discussing mass medication of food animals).

60. Stuart B. Levy, *The Challenge of Antibiotic Resistance*, 278 SCI. AM. 46, 46 (1998).

61. *Id.*

62. Antibiotics and Sulfonamide Drugs in the Feed of Animals, 38 Fed. Reg. 9811, 9811-13 (Apr. 20, 1973) (describing emerging evidence of risks associated with “subtherapeutic” uses of antibiotics in livestock); *id.* at 9813 (equating “subtherapeutic” uses with “increased rate of gain” and “disease prevention” uses).

63. Penicillin-Containing Premixes, 42 Fed. Reg. 43,772, 43,792 (Aug. 30, 1977); Tetracycline (Chlortetracycline and Oxytetracycline)-Containing Premixes, 42 Fed. Reg. 56,264, 56,288 (Oct. 21, 1977).

64. FDA, GUIDANCE FOR INDUSTRY #152, EVALUATING THE SAFETY OF ANTIMICROBIAL NEW ANIMAL DRUGS WITH REGARD TO THEIR MICROBIOLOGICAL EFFECTS ON BACTERIA OF HUMAN HEALTH

The Agency expressed similar concerns in its 2012 order prohibiting certain extra-label uses of cephalosporin drugs in certain food-producing animals.⁶⁵ There, it worried about using these drugs in whole herds or flocks of animals even when the use was intended to prevent infection, not to promote production.⁶⁶

Recently, however, the FDA has quietly and without explanation separated subtherapeutic or nontherapeutic uses into two, expressing a desire to phase out one (production uses) while still embracing the second (prevention uses). Indeed, in between its draft Guidance #209 and its final version of the guidance, the FDA dropped the “subtherapeutic” and “nontherapeutic” nomenclature altogether, tersely explaining in the final guidance that these terms lacked “sufficient clarity.”⁶⁷

But the FDA’s sudden and unexplained departure from its prior expressions of concern about the practice of administering low doses of antibiotics to whole herds and flocks of animals—regardless of the purpose of such administration—has introduced more confusion than clarity. As the Natural Resources Defense Council explained in comments on the FDA’s recent proposals, there is a great deal of overlap in the doses given for purposes of production and prevention.⁶⁸ To microorganisms, it does not matter whether the person giving the drugs is trying to promote growth or to prevent infection; the microbiological effect is the same. Scientifically, therefore, it is hard to understand why the FDA is trying to put the brakes on production uses while going full steam ahead with prevention uses.

Even if such a distinction were scientifically justified, a practical concern is that drug companies that voluntarily withdraw production uses for medically important antibiotics might simply sell as many antibiotics as ever, but for purposes of prevention rather than production. In fact, unless one believes this is exactly

CONCERN (2003), *available at* <http://tinyurl.com/n6bsaum> (introducing a risk-based framework for evaluating applications for approval of *new* antimicrobial animal drugs, unlike the other guidance documents discussed here, which relate to the FDA’s treatment of already-approved antimicrobial animal drugs).

65. New Animal Drugs; Cephalosporin Drugs; Extralabel Animal Drug Use; Order of Prohibition, 77 Fed. Reg. 735 (Jan. 6, 2012) (to be codified at 21 C.F.R. pt. 530).

66. *Id.* at 740.

67. GUIDANCE FOR INDUSTRY #209, *supra* note 11, at 4 n.3.

68. NRDC Comments Letter, *supra* note 24, at 3-4, Ex. 1. For this reason, it is impossible to identify what percentage of the antibiotics currently administered to livestock is used for growth promotion as opposed to disease prevention.

what will happen, it is hard to make sense of the drug company Zoetis's statement that it does not expect its participation in the FDA's program to have a significant effect on its revenues or a spokesperson's comment that it is "impossible to say" if overall antibiotic use would diminish if production uses ceased.⁶⁹ Such statements have fueled suspicion that even drug makers that do volunteer for the FDA's program may simply switch from production to prevention as a rationale for continuing to do what they've done for decades⁷⁰—and, perhaps, make this switch as a marketing strategy as well. In fact, Phibro Animal Health has already indicated that, while it supports the FDA's judicious use program in principle, it intends to seek new, prevention-related indications for its drug, virginiamycin—probably using the very same dosages now administered for production uses.⁷¹

The FDA's Guidance #213 seems intended in part to dampen the concern that drug companies and agricultural producers will simply switch to prevention uses of medically important antibiotics. As noted above, the Agency states that it expects veterinarians to approve the use of medically important antibiotics for "prevention purposes" only to "prevent disease based on specific, known risk."⁷² The Agency's detailed list of the considerations relevant to determining whether such a risk is present seems reassuring.⁷³ At first glance, the length and specificity of this list appear to make it rather difficult for a veterinarian to justify administering antibiotics to food animals for prevention purposes.

However, consider the breadth of veterinary discretion entailed in the catch-all category of "other factors" beyond those explicitly listed and even in the specific category of host and environmental factors, which include, respectively, nutrition and ventilation.⁷⁴ Indeed, the FDA hints at the breadth of discretion afforded by its criteria when it gives an example of what it would consider a judicious preventive use of a medically significant antibiotic:

69. Beth Hoffman, *New FDA 'Rules' Not Likely to Reduce Antibiotic Use on Farm*, FORBES (Dec. 13, 2013, 10:08 AM), <http://tinyurl.com/qbuogad>.

70. See, e.g., Peter Lehner, *FDA's Plan for Antibiotic Abuse on Industrial Farms: A Weak Effort in the Fight Against Superbugs*, NRDC SWITCHBOARD (Dec. 16, 2013), <http://tinyurl.com/lvz4zsa>.

71. Coulter, *supra* note 45.

72. GUIDANCE FOR INDUSTRY #213, *supra* note 1, at 7.

73. *Id.*

74. *Id.*

[I]f a veterinarian determines, based on the client's production practices and herd health history, that cattle being transported or otherwise stressed are more likely to develop a certain bacterial infection, preventively treating these cattle with an antimicrobial approved for prevention of that bacterial infection would be considered a judicious use.⁷⁵

Allowing animals' state of being "stressed," with the increased susceptibility to infection that stress brings, to count as a reason for feeding antibiotics to whole herds or flocks of animals threatens to eliminate the "judicious" part of the FDA's "judicious use" policy. A signature feature of modern industrial animal operations is that the animals in such operations are "stressed."⁷⁶ By allowing "stress" to justify prevention uses of antibiotics in food animals, the FDA risks undoing any progress it might have made by seeking to phase out production uses.

It is possible, however, that some drug makers have not asked the FDA to approve indications for use of their drugs to prevent particular infections; it is possible that they have rested with production uses alone, or with only a select list of infections potentially prevented through herd- and flock-wide use of their products. Perhaps in those cases, the FDA's caution that an antibiotic must be approved for a particular infection in order to be used to prevent that infection would have some bite.

But here, the FDA comes to the rescue of the drug makers again. Indeed, the Agency devotes a substantial part of its Guidance #213 to describing the process it will use to approve new therapeutic indications for antibiotics used for production uses. "In some cases," the FDA says, "it has been suggested that there could be a therapeutic benefit associated with production use of a drug."⁷⁷ In such cases, the FDA continues, "where scientific evidence demonstrates a therapeutic benefit associated with the use of the drug for treating, controlling, or preventing a particular disease, sponsors could wish to seek new therapeutic indications to fill the

75. *Id.*

76. For harrowing descriptions of typical living conditions of various food-producing animals, see *Factory Farming*, FARM SANCTUARY, <http://tinyurl.com/pnqjf88> (last visited June 12, 2014).

77. GUIDANCE FOR INDUSTRY #213, *supra* note 1, at 11.

therapeutic needs of animals.”⁷⁸ These passages seem a little tongue-tied, as they appear to conflate production uses with therapeutic uses, but a close reading of the text suggests the conflation is intended; the FDA appears to be contemplating approval of new therapeutic reasons for continuing production uses. The Agency explains in great detail how it will treat applications to include such uses on drug labels.⁷⁹

By specifying a process for handling drug companies’ requests for new indications for livestock antibiotics, the FDA effectively confirms that skeptics’ worries that production uses will simply shift to prevention uses are justified; the Agency is actively planning for this shift.

Moreover, in doing so, the Agency weakens the guidelines it has already set for approving new medically important animal antibiotics. The FDA’s Guidance #152 established standards for approving new medically important animal antibiotics. That guidance appears to describe a more constrained process for approving such uses than the FDA’s recent Guidance #213 does.⁸⁰ Indeed, if the processes were identical, the FDA could have rested in Guidance #213 with a simple reference to and incorporation of the process and standards specified in Guidance #152. Instead, Guidance #213 is far vaguer than Guidance #152 on indicators of the risks of mass medication, such as dose levels and duration of dose. Where Guidance #152 specifies, in number of days, durations of dosing that indicate low, medium, and high use, and invites attention to exactly how many animals are dosed at once (individual animals, select groups, or whole herds or flocks),⁸¹ Guidance #213 gestures toward dose levels and animals dosed without going into specifics.⁸² In fact, tellingly, whereas the draft version of Guidance #213 stated that the specified therapeutic dose level for a new therapeutic indication of a medically important antibiotic would “most likely” be “a higher dose than that approved for the current weight gain/feed efficiency indications,”⁸³ the final version of the

78. *Id.*

79. *Id.* at 11-15.

80. NRDC Comments Letter, *supra* note 24, at 4-5.

81. FDA, *supra* note 64, at 23 tbl. 7.

82. GUIDANCE FOR INDUSTRY #213, *supra* note 1, at 12-14.

83. FDA, DRAFT GUIDANCE FOR INDUSTRY #213, NEW ANIMAL DRUGS AND NEW ANIMAL DRUG COMBINATION PRODUCTS ADMINISTERED IN OR ON MEDICATED FEED OR DRINKING WATER OF FOOD-PRODUCING ANIMALS: RECOMMENDATIONS FOR DRUG SPONSORS FOR VOLUNTARILY ALIGNING PRODUCT

guidance omits this qualification entirely.⁸⁴ The final guidance also makes clear that herd- and flock-wide administration of antibiotics to food animals is still acceptable so long as “necessary.”⁸⁵

In the final version of Guidance #209, describing the FDA’s “judicious use” policy, the FDA indicated why it thought Guidance #152 should be applied to new animal drugs but perhaps not to already-approved animal drugs. “On the pre-approval side,” the FDA explained, the process announced in Guidance #152 “is taken into consideration by drug sponsors upstream in the drug development process and, in effect, steers product development in a direction that is most consistent with the guidance.”⁸⁶ Post-approval, however, the FDA’s examination of already-approved products for their consistency with the principles of Guidance #152 would, the FDA emphasized, run headlong into section 512(e)(1) of the Food, Drug, and Cosmetic Act⁸⁷—the same regulatory provision on drug safety that the Agency has repeatedly characterized as ineffective. The Agency’s unwillingness to take on existing approvals ought not, however, extend to applications for new indications for medically important antibiotics. It is hard to find a justification for the FDA’s more solicitous treatment of new indications for already-approved antibiotics besides fealty to the industry the Agency is supposed to be regulating.

In sum, the FDA’s preservation of production uses of medically important antibiotics lacks coherence as a scientific matter but exudes coherence as a political matter. The Agency appears to hope that its accompanying embrace of veterinary oversight of the administration of these antibiotics to food animals will prevent production uses from achieving the same level of profligacy as prevention uses have. The effectiveness of this oversight is, however, threatened by the Agency’s simultaneous relaxation of requirements relating to veterinary oversight of antibiotic use.

C. Veterinary Oversight

A third problem with the FDA’s framework is that the FDA is

USE CONDITIONS WITH GFI #209, at 11 (2012) (on file with author).

84. GUIDANCE FOR INDUSTRY #213, *supra* note 1, at 13 (explaining that new indications should “specify a therapeutic dose level,” without more).

85. *Id.*

86. GUIDANCE FOR INDUSTRY #209, *supra* note 11, at 19.

87. *Id.*

relaxing the requirements for veterinary oversight of the administration of livestock antibiotics at the same moment as it is proposing to rely on veterinarians to police its new policies.

The FDA issued a proposed rule relaxing the requirements for veterinary feed directives on the same day it issued its final Guidance #213.⁸⁸ The two documents are, for the FDA, inextricably linked. The FDA believes that its bringing therapeutic uses of medically important antibiotics under the oversight of veterinarians will not work unless it relaxes the requirements for such oversight.⁸⁹ Reinforcing the link between these initiatives, the Agency announces in Guidance #213 that its whole program may extend beyond the three-year period it plans if the measures on veterinary feed directives are delayed.⁹⁰

A central feature of the FDA's proposed rule is the FDA's proposal to eliminate the federal framework for the "veterinarian-client-patient relationship" (VCPR) and to replace it with reliance on state-by-state veterinary licensing and practice requirements.⁹¹ Eliminating the VCPR requirement means that veterinarians would be able to issue veterinary feed directives without seeing or examining the actual animals subject to the directives. Current regulations provide that a valid VCPR "can exist only when the veterinarian has recently seen and is personally acquainted with the keeping and care of the animal(s) by virtue of examination of the animal(s), and/or by medically appropriate and timely visits to the premises where the animal(s) are kept."⁹² The FDA's proposed rule jettisons this provision. As if to punctuate the point, the FDA explicitly states that "*oversight*" of animals subject to veterinary feed directives is sufficient for its purposes, whereas previously, the Agency had required (as the relevant statutory text does) veterinary "*supervision*" of such animals.⁹³

Relaxing the extent of oversight required for veterinary feed directives dovetails badly with the FDA's broad protection of

88. Veterinary Feed Directive, 78 Fed. Reg. 75,515 (proposed Dec. 12, 2013) (to be codified at 21 C.F.R. pts. 514, 558).

89. GUIDANCE FOR INDUSTRY #213, *supra*, note 1, at 9 ("[I]mplementing changes to streamline existing VFD requirements is pivotal to facilitating the transition to greater veterinary oversight (i.e., from OTC to VFD marketing status) for many of these products.").

90. *Id.*

91. Veterinary Feed Directive, 78 Fed. Reg. at 75,516, 75,518-19 (emphasis added).

92. 21 C.F.R. § 530.3(i) (2013).

93. Veterinary Feed Directive, 78 Fed. Reg. at 75,518.

production uses of medically important antibiotics. A person phoning in a medication directive from afar will of necessity rely on more generic indicators of disease risk than a person on site. Generic conditions of stress for modern food animals—unsanitary, crowded living conditions, poor nutrition⁹⁴—can be identified from afar, and will satisfy the FDA's broad criteria for "judicious" use of antibiotics for prevention purposes. The unhealthy generic conditions of modern agricultural animals thus become a catch-all justification for continued unhealthy wastage of antibiotics' power to protect us.

The FDA's proposed reliance on state-law veterinary licensing and practice requirements provides little comfort. The FDA asserts that eliminating the federal framework for the VCPR "would enable the veterinary profession and individual states to adjust the specific criteria for a VCPR to appropriately align with current practice standards, technological and medical advances, and other regional considerations."⁹⁵ As the Johns Hopkins Center for a Livable Future has pointed out in comments on the proposed rule, however, the FDA has offered no reason to believe that the current VCPR conflicts with any current practice standard or any technological or medical advance.⁹⁶ Nor has the FDA explained why "regional considerations"—including, most prominently, the dearth of veterinarians in "remote geographical areas"—justify removing the VCPR for all livestock producers.⁹⁷ More fundamentally, as the Center for a Livable Future has observed, existing state veterinary licensing and practice requirements will not fill the gap created by eliminating the federal VCPR. Four states do not even have VCPR requirements at all. Thirty-four additional states do not apply their VCPR requirements to VFD products.⁹⁸ In fully thirty-eight states, therefore, removal of the federal VCPR will leave nothing but a hole in the protections theoretically afforded by veterinary oversight.

The FDA's proposed rule on veterinary feed directives loosens

94. Robert S. Lawrence, *The FDA Did Not Do Enough to Restrict Antibiotics Use in Animals*, THE ATLANTIC (Apr. 16, 2012), <http://tinyurl.com/8xch8yc>.

95. Veterinary Feed Directive, 78 Fed. Reg. at 75,518.

96. Letter from Robert S. Lawrence, M.D., Dir. for The Johns Hopkins Ctr. for a Livable Future, et. al., to FDA, at 2 (Mar. 12, 2014), available at <http://tinyurl.com/knjd72e> [hereinafter Johns Hopkins Ctr. for a Livable Future] (commenting on Veterinary Feed Directive Proposed Rule (Docket No. FDA-2010-N-0155)).

97. Veterinary Feed Directive, 78 Fed. Reg. at 75,518.

98. Johns Hopkins Ctr. for a Livable Future, *supra* note 96, at 3, 7 tbl. 1.

existing requirements in other ways as well. No longer will veterinarians be required to include on feed directives even their license numbers or the amount of drugs being administered.⁹⁹ The information that will still be required bears little connection to the purportedly targeted criteria for using antibiotics to prevent infections in whole herds and flocks of animals.¹⁰⁰ And, perhaps most significantly, veterinarians will no longer be required to keep their records on VFDs for two years; one year suffices under the FDA's proposed rule.¹⁰¹ Yet, as the Center for a Livable Future has noted, the relaxed recordkeeping requirement will reduce the FDA's ability to track overuse of livestock antibiotics and is not justified by the FDA's unsupported concerns about recordkeeping burdens.¹⁰²

Veterinary oversight of the administration of medically important antibiotics to livestock will be a useful stand-in for FDA oversight only if veterinarians actually exercise useful oversight. The FDA's proposed relaxation of the requirements for veterinary oversight does not hold high promise in this regard. Indeed, as explained above, the FDA's proposal on veterinary oversight contains so many logical and evidentiary gaps that, if it were finalized as proposed, a credible case could be made that the rule would be arbitrary and thus unlawful.

D. Keeping the Public in the Dark

A final, overarching problem with the FDA's plan for addressing antibiotics used in animal feed and water is that the plan will unfold largely in secret.¹⁰³

In Guidance #213, the FDA promises just three measures to keep the public apprised of its work. First, the Agency promises to post (and has posted) on its website a list of the drug products initially affected by its guidance document.¹⁰⁴ Second, the Agency will, after

99. Veterinary Feed Directive, 78 Fed. Reg. at 75,520, 75,521.

100. *Id.* at 75,527 (declining to require a veterinarian issuing veterinary feed directive to include information on specific risk factors for infection, and permitting, but not requiring, a veterinarian to include information on the location, age, weight, and "[a]ny other information the veterinarian deems appropriate to identify the animals").

101. *Id.* at 75,520.

102. Johns Hopkins Ctr. for a Livable Future, *supra* note 96, at 5.

103. The discussion that follows draws from Lisa Heinzerling, *Secrecy Protects Only Laggards: Why the FDA Should Disclose Which Drug Companies Volunteer for its "Judicious Use" Policy for Livestock Antibiotics*, CPRBLOG (Jan. 6, 2014), <http://tinyurl.com/k5uscs7>.

104. See GUIDANCE FOR INDUSTRY #209, *supra* note 1, at 9; *supra* text accompanying note

the three-month period in which drug sponsors are to inform the Agency if they will take part in the Agency's voluntary initiative, "publish summary information to provide an indicator of the level of engagement of affected drug sponsors in the voluntary process."¹⁰⁵ Third, the FDA will notify the public "of completed changes to affected products through publication of approval of supplemental new drug applications."¹⁰⁶

This is meager transparency. It is nice to have the list of drug products affected by the FDA's guidance document. It is also good that, in March 2014, the FDA provided a list of the twenty-five companies that had agreed to engage with the Agency in phasing out production uses of their medically important livestock antibiotics. But beyond this initial burst of transparency, the Agency has promised only to provide "public updates on a periodic basis."¹⁰⁷ And the FDA's promise to tell the public of completed changes to affected products adds nothing to what the public already would expect; the FDA's own regulations require it to notify the public of approval of drug applications.¹⁰⁸

Beyond the ill-specified periodic "public updates" the FDA has promised, it appears that the FDA will now essentially go to ground for three years while it works things out privately with the drug sponsors. The FDA does not, as a general rule, tell the public when it has received a supplemental drug application,¹⁰⁹ and it does not disclose the status of any application it has received until the application is finally approved.¹¹⁰ Even once the application is approved, the Agency does not typically make available the documents that have been exchanged between the Agency and drug sponsor during the application process or let the public know what the Agency-sponsor interactions involved.¹¹¹ The process is private, not public, and the FDA appears to intend to keep it that way in this case. In a situation rife with potential for coziness between the government and the regulated industry, this extreme level of

49.

105. GUIDANCE FOR INDUSTRY #213, *supra* note 1, at 9.

106. *Id.*

107. FDA, *supra* note 40.

108. 21 C.F.R. § 514.11(e) (2013).

109. *Id.* § 514.11(b).

110. *Id.*

111. *Id.* § 514.11(3) (providing for public disclosure, after approval, of some materials submitted in relation to a new animal drug application).

secrecy does not augur well for the success of the “judicious use” program.

IV. RECOMMENDATIONS FOR IMPROVEMENT

How can the FDA do better?

The best course for the FDA would be to turn away from its request for voluntary forbearance by drug companies and toward regulatory action. The legal premise of the FDA’s rejection of the regulatory route is that in order to withdraw its approvals for certain uses of medically important antibiotics in food-producing animals, it must hold a formal, trial-type hearing for every affected drug.¹¹² As I have explained in a previous article, however, this legal premise is mistaken. In clinging to this incorrect legal premise, the FDA has ignored decades of developments in administrative law that have dramatically cut back on requirements for formal hearings.¹¹³ The Agency has also over-read statutory language requiring only a “hearing”—not a formal, trial-type hearing—before withdrawing existing approvals on safety-related grounds.¹¹⁴ And it has failed to explain why it has insisted on reading its statute (the Food, Drug, and Cosmetic Act) to require time- and resource-intensive hearings rather than interpreting it to give the Agency enough procedural flexibility to do its job of protecting public health.¹¹⁵ The choice is not, as the FDA would have it, between voluntary measures and regulation preceded by years-long formal hearings. The Agency could make the safety-based determinations necessary to justify withdrawing certain uses of medically important antibiotics without holding formal, trial-type hearings.

The procedural flexibility the Agency enjoys will come in particularly handy if the Second Circuit upholds the district court’s ruling ordering the Agency to complete the proceedings, announced in 1977, to withdraw approvals for subtherapeutic uses of penicillin and tetracycline in livestock.¹¹⁶ The FDA’s appeal of the district court’s ruling was argued in February 2013; a decision could come any day.

Even if the FDA wins the case on appeal and even if it decides to

112. Heinzerling, *supra* note 6, at 1012-13, 1019-20.

113. *Id.* at 1013-19.

114. *Id.* at 1019-26.

115. *Id.* at 1025-26.

116. *NRDC v. FDA*, 872 F. Supp. 2d 318 (S.D.N.Y. 2012).

adhere to its voluntary approach, that approach can be improved in several respects. The first, and easiest, has to do with transparency. Voluntary programs work, if at all, when volunteers are rewarded and laggards are called out. The public deserves good information, at every step of the way, about the progress of the FDA's voluntary program and the extent of drug sponsors' cooperation with it. Improved transparency will not fix the FDA's program, as the program suffers from defects that go beyond secrecy. But, with this change, at least we would know sooner rather than later whether this initiative is doomed to fail because too few companies are fully onboard with the FDA's voluntary program, or too many have chosen to phase out production uses while simultaneously ramping up prevention uses.

Another way to improve the FDA's program would be to strengthen the veterinary oversight the Agency is asking the drug companies to accept. As it is now, the Agency is moving in the opposite direction, relaxing current requirements for such oversight. But if the FDA's attempt to move away from production uses of antibiotics for livestock is to have any effect, and not simply encourage livestock producers to switch uses to "prevention" rather than "production," there must be some real limit to the prevention uses allowed. In finalizing the rule on veterinary feed directives, the FDA should align the rule's requirements with the stated aim of its guidance for drug companies, which is to make sure that medically important antibiotics are used to prevent only "specific, known risk."¹¹⁷

V. CONCLUSION

Even with improvements along the lines I have suggested, I worry that the FDA's voluntary program will not achieve appreciable gains. I hope I am wrong. I hope the FDA's plan to phase out production uses of, and phase in veterinary oversight for, medically important antibiotics administered through the feed and water of food-producing animals succeeds. I hope the companies that make these antibiotics follow through their initial signals that they will agree to phase out production uses and phase in veterinary oversight. I hope they do not simply replace production uses with prevention uses. I hope that, despite the broad discretion given to

117. GUIDANCE FOR INDUSTRY #213, *supra* note 1, at 7.

them in the FDA's recent initiatives, veterinarians exercise real caution in administering antibiotics to whole herds and flocks of animals in the absence of an active infection. I hope that once the FDA comes above ground again and announces what happened during the three years it interacted privately with drug sponsors, it will have good news to tell us.

Even more, I hope that the Second Circuit, now reviewing the district court's ruling that the FDA unlawfully declined to use its regulatory powers to address antibiotics used in animal feed and water, will see through the FDA's pretense of bold action and uphold the district court's order to the FDA to do its job.